FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 27, 2026

Coverage: 2026-06-20 – 2026-06-26 (FDA publish date basis)

Published: July 04, 2026

Note: FDA typically publishes approvals 1–2 weeks after decision date. This report reflects the latest available data as of publication.

This Week at FDA

This week's FDA activity highlights a strategic industry focus on maximizing existing assets, with an unusually high number of ten label expansions overshadowing the single new molecular entity approval for Lumvoa's Veligrotug. Heightened FDA enforcement, evidenced by four significant warning letters, underscores the increasing compliance risks in a complex global supply chain. This trend is further emphasized by the substantial volume of activity from Asian firms, which signals accelerating international competition and the critical need for Western companies to monitor the evolving global landscape for both threats and partnership opportunities.

1	2	10	197	4
NME Approvals	Total Drug Approvals	New Indications	510(k) Clearances	PMA Originals

63

Asian Co. Events

🌏 Asian Company Watch — FDA Activity This Week

Japanese, Korean, and Chinese companies with FDA approvals or clearances this week — and what it means for the competitive landscape.

🇨🇳 Shenzhen Konmed Technology Co., Ltd. China

> Pelvic Muscle Trainer (KM510, KM516B)

Shenzhen Konmed Technology Co., Ltd. from China has received 510(k) clearance for its Pelvic Muscle Trainer, a device designed for strengthening pelvic floor muscles.

> **Intelligence:** This clearance provides a Chinese device manufacturer with access to the growing US market for at-home women's health and wellness devices.

🇰🇷 Megagen Implant Co., Ltd. South Korea

> MegaGen Zygoma Dental Implant System

South Korea's Megagen Implant Co., Ltd. has obtained 510(k) clearance for its MegaGen Zygoma Dental Implant System, intended for use in the upper jaw with severe bone loss.

> **Intelligence:** The introduction of a specialized zygomatic implant could help Megagen target a high-value niche for complex cases within the competitive US dental implant market.

🇨🇳 Suzhou and Science & Technology Development Corp. China

> AND Medical Femoral Nail System (PFNA01); AND Medical Femoral Nail System (PFNA02)

The Chinese firm Suzhou and Science & Technology Development Corp. received 510(k) clearance for its AND Medical Femoral Nail System used to treat fractures of the femur.

> **Intelligence:** This clearance adds to the growing number of Chinese orthopedic trauma device manufacturers securing US market access, potentially increasing options for price-sensitive providers.

🇨🇳 Shantou Institute of Ultrasonic Instruments Co., Ltd. China

Portable DR Imaging System

Shantou Institute of Ultrasonic Instruments Co., Ltd. of China gained 510(k) clearance for its Portable Digital Radiography (DR) Imaging System.

Intelligence: Clearance for a portable DR system may position the company to compete in US outpatient, mobile, or veterinary imaging segments where mobility and cost are key factors.

🇯🇵 FUJIFILM Healthcare Americas Corporation Japan

Synapse PACS (7.6.0)

The US-based entity of Japan's Fujifilm Group, FUJIFILM Healthcare Americas Corporation, received 510(k) clearance for version 7.6.0 of its Synapse Picture Archiving and Communication System (PACS).

Intelligence: Continuous software updates to its core Synapse PACS platform are crucial for Fujifilm to maintain its competitive position and support its extensive installed base in the US hospital imaging market.

🇨🇳 Zhejiang Innuovo Rehabilitation Devices Co.,Ltd China

Power Wheelchair (W5915B, W5915C, W5915D)

China's Zhejiang Innuovo Rehabilitation Devices Co., Ltd. has secured 510(k) clearance for several models of its power wheelchair.

Intelligence: This clearance broadens the company's portfolio of personal mobility devices available to compete in the US durable medical equipment (DME) market.

🇰🇷 GC America, Inc. South Korea

SRGC-06

GC America, Inc., the US subsidiary of a Korean corporation, has received 510(k) clearance for its SRGC-06, a dental restorative material.

Intelligence: GC America's continued 510(k) activity for new dental materials reinforces its strategy of maintaining a broad and updated product portfolio for its US distribution network.

🇰🇷 Vieworks Co., Ltd. South Korea

VIVIX-S 4386W (FXRD-4386WA)

Vieworks Co., Ltd. of South Korea has obtained 510(k) clearance for its VIVIX-S 4386W, a flat panel digital X-ray detector.

Intelligence: Adding another model to its extensive VIVIX line of digital detectors may strengthen Vieworks' position as a key component supplier to medical imaging system integrators in the US.

🇨🇳 Micro-Energy Medical Technology Co., Ltd. China

Hemolase Fiber (Hemo-R-0.40-2.5/Hemo-R-0.60-2.5/Hemo-R-0.40-1.8/Hemo-R-0.60-1.8)

China's Micro-Energy Medical Technology Co., Ltd. received 510(k) clearance for its Hemolase Fiber, a sterile, disposable optical fiber for use with medical lasers.

Intelligence: Securing clearance for a consumable laser fiber could be a strategic step for the company to build a recurring revenue stream within the US surgical market.

🇨🇳 Guangzhou Rebornendo Medical Instrument Co., Ltd. China

Curing Light (M-Cure 6)

Guangzhou Rebornendo Medical Instrument Co., Ltd. from China has received 510(k) clearance for its M-Cure 6, a light-emitting diode (LED) dental curing light.

Intelligence: This clearance allows another Chinese manufacturer to enter the crowded US market for basic dental equipment, likely competing on price point.

🇨🇳 Shenzhen Ziqing Medical Equipment Co., Ltd. China

Wrist Blood Pressure Monitor (XW-05)

China's Shenzhen Ziqing Medical Equipment Co., Ltd. has obtained 510(k) clearance for its XW-05 Wrist Blood Pressure Monitor.

Intelligence: This clearance positions the company to compete in the US over-the-counter and direct-to-consumer markets for personal health monitoring devices.

🇨🇳 Shenzhen Root Innovation Technology Co., Ltd. China

> Momcozy Wearable Breast Pump (BP311, BP311-A, BP311-B, BP311-C, BP311-D)

Shenzhen Root Innovation Technology Co., Ltd. from China received 510(k) clearance for its Momcozy Wearable Breast Pump.

> **Intelligence:** This clearance for the popular direct-to-consumer Momcozy brand formalizes its entry into the regulated US medical device market, signaling a move to solidify its market presence.

🇨🇳 Guangdong Newdermo Biotech Co., Ltd. China

> LED Light Therapy Mask (K9C-TK, K9C-K, K9P-YK, K9P-K, FM-03BK, FM-09K)

China's Guangdong Newdermo Biotech Co., Ltd. has gained 510(k) clearance for its LED Light Therapy Mask, intended for treating facial acne.

> **Intelligence:** The clearance indicates a strategy to target the high-growth US 'med-aesthetic' consumer market, which bridges the gap between cosmetics and medical devices.

🇹🇼 Oneness Biotech Co., Ltd. Taiwan

> Bonvadis®

Oneness Biotech Co., Ltd. of Taiwan has received 510(k) clearance for Bonvadis®, a topical cream for managing diabetic foot ulcers.

> **Intelligence:** This clearance for a novel wound care product marks a significant entry for the Taiwanese biotech firm into the high-value US chronic care market.

🇨🇳 Hua Yue Medical Technology Co., Ltd. China

> Assisted Reproduction Laser System (Model ILS-400M)

China's Hua Yue Medical Technology Co., Ltd. has secured 510(k) clearance for its Assisted Reproduction Laser System, used in fertility treatments.

> **Intelligence:** Entry into the specialized US market for IVF and fertility clinic capital equipment signals growing sophistication among Chinese medtech manufacturers.

🇹🇼 Socko Medical Co., Ltd. Taiwan

> “Socko” Vimax Spinal Fixation System

🇨🇳 Foshan Pingchuang Medical Technology Co., Ltd. China

Non-Sterile Ultrasound Gel Sterile Ultrasound Gel

China's Foshan Pingchuang Medical Technology Co., Ltd. received 510(k) clearance for both sterile and non-sterile ultrasound gels.

Intelligence: Gaining clearance for a high-volume, low-cost consumable like ultrasound gel may support a broader market entry strategy focused on supplying basic medical disposables to US healthcare facilities.

🇨🇳 Honsun (Nantong) Co., Ltd. China

Portable Oxygen Concentrator

Honsun (Nantong) Co., Ltd. of China has secured 510(k) clearance for its Portable Oxygen Concentrator.

Intelligence: This clearance allows the company to address the US home healthcare market for respiratory therapy, a segment with growing demand from an aging population.

🇨🇳 Shenzhen Root Innovation Technology Co., Ltd. China

Momcozy Wearable Breast Pump (BP420, BP420-A, BP420-B, BP420-C, BP420-D)

China's Shenzhen Root Innovation Technology Co., Ltd. received a second 510(k) clearance for another model of its Momcozy Wearable Breast Pump.

Intelligence: A second 510(k) clearance in a short period for its Momcozy brand suggests a strategy by Root Innovation to rapidly build out a portfolio of wearable breast pump models for the US consumer market.

🇨🇳 Beijing Fule Science & Technology Development Co., Ltd. China

Fule Metallic Lockable Intramedullary Nail Systems

Beijing Fule Science & Technology Development Co., Ltd. from China has obtained 510(k) clearance for its metallic lockable intramedullary nail systems for fracture fixation.

Intelligence: This clearance for a trauma fixation system broadens the company's orthopedic product offerings for the US market, adding to its portfolio of spinal and trauma devices.

🇹🇼 Hivox Biotek, Inc. Taiwan

> TENS / EMS DEVICE (FT-247 Series) (FT-247, FT-237)

Hivox Biotek, Inc., a Taiwanese company, received 510(k) clearance for its TENS/EMS device for pain relief and muscle stimulation.

> **Intelligence:** This clearance allows the Taiwanese company to compete in the US over-the-counter and physical therapy markets for pain management and muscle stimulation devices.

🇨🇳 Hunan Ruijiong Biotech Co., Ltd. China

> KT Airway Clearance Device II (KT-3); KT Airway Clearance Device II (KT-5)

China's Hunan Ruijiong Biotech Co., Ltd. has gained 510(k) clearance for its KT Airway Clearance Device II, which helps loosen mucus in the lungs.

> **Intelligence:** This product clearance positions the company to enter the US market for respiratory care devices, targeting patients with conditions like cystic fibrosis or COPD.

🇨🇳 Hubei Yjt Technology Co.,Ltd China

> Laser Hair Growth System (Laser Cap 128, Laser Helmet 272, Laser Helmet 352, Laser Helmet 552, Laser Helmet 500)

Hubei Yjt Technology Co., Ltd. of China has received 510(k) clearance for its Laser Hair Growth System, available in multiple helmet and cap models.

> **Intelligence:** Clearing multiple models of a laser hair growth system indicates a strategy to target the US direct-to-consumer aesthetic device market with a range of product options and price points.

🇯🇵 Fujifilm Corporation Japan

> FUJIFILM Endoscope Model EB-840S; FUJIFILM Endoscope Model EB-840T

Japan's Fujifilm Corporation has obtained 510(k) clearance for two new models of its video bronchoscopes, the EB-840S and EB-840T.

> **Intelligence:** The addition of new endoscope models reinforces Fujifilm's position as a major competitor in the US gastrointestinal and surgical visualization market, directly rivaling other established players.

🇨🇳 Zdeer Technology (Henan) Co., Ltd. China

> Laser Hair Growth Device (F21151, F21152, F21153, F21154, F21155, F21156, F21157, F21158, F21159)

China's Zdeer Technology (Henan) Co., Ltd. secured 510(k) clearance for a series of laser hair growth devices.

> **Intelligence:** This clearance for numerous device models suggests a strategy to offer a wide product range in the competitive US at-home aesthetic device market.

🇨🇳 ZheJiang Decans Medical Devices Co., Ltd. China

> HERA Interlocking Intramedullary Nailing System

ZheJiang Decans Medical Devices Co., Ltd. from China received 510(k) clearance for its HERA Interlocking Intramedullary Nailing System for long bone fractures.

> **Intelligence:** This clearance further populates the US orthopedic trauma market with options from Chinese manufacturers, potentially increasing competition in the value segment.

🇨🇳 Shenzhen Kaiyan Medical Equipment Co., Ltd. China

> LED Neck Beauty Mask (ZLD-66A,ZLD-90E,ZLD-130,ZLD-180H)

China's Shenzhen Kaiyan Medical Equipment Co., Ltd. gained 510(k) clearance for its LED Neck Beauty Mask, intended for treating wrinkles on the neck.

> **Intelligence:** This clearance for a niche aesthetic device targeting the neck area demonstrates the increasing specialization of Chinese manufacturers aiming for the US consumer wellness market.

🇰🇷 Medpark Co., Ltd. South Korea

> BOSS

South Korea's Medpark Co., Ltd. has received 510(k) clearance for its BOSS, a guided surgery system for dental implant placement.

> **Intelligence:** This clearance could enable Medpark to introduce its dental surgical guidance technology to the US market, expanding the range of Korean-made digital dentistry solutions.

🇰🇷 Medyssey Co, Ltd. South Korea

> NeckTune™ 3D SA Cervical Cage

🇰🇷 Jpi Healthcare Co, Ltd. South Korea

> DRE Duo

South Korea's Jpi Healthcare Co, Ltd. secured 510(k) clearance for the DRE Duo, a portable X-ray system.

> **Intelligence:** This clearance may allow JPI Healthcare to expand its offerings in the US from core imaging components to complete system solutions, particularly for the veterinary or specialized medical markets.

🇰🇷 Crescom Co., Ltd. South Korea

> MediAI-OA

Crescom Co., Ltd., a South Korean company, has received 510(k) clearance for MediAI-OA, an AI software that assists in diagnosing osteoarthritis from knee X-ray images.

> **Intelligence:** The clearance of an AI-based software for osteoarthritis analysis highlights a key trend of Korean medtech firms moving into the higher-value medical software and diagnostics-as-a-service space in the US.

🇨🇳 Gimbo Medical Technology Shenzhen Co., Ltd. China

> Giftlife Single Lumen Oocyte Retrieval Needle, Giftlife Double Lumen Oocyte Retrieval Needle

China's Gimbo Medical Technology Shenzhen Co., Ltd. has obtained 510(k) clearance for its single and double lumen oocyte retrieval needles used in IVF procedures.

> **Intelligence:** This clearance for specialized IVF consumables positions the company to supply the growing US fertility clinic market with essential disposable devices.

🇨🇳 Zhongshan Sulenz Intelligent Technology Co., Ltd. China

> Electric Wheelchair (S500-6)

Zhongshan Sulenz Intelligent Technology Co., Ltd. from China received 510(k) clearance for its S500-6 model electric wheelchair.

> **Intelligence:** This clearance adds another Chinese manufacturer to the list of suppliers for the US durable medical equipment (DME) market, specifically in personal mobility.

🇨🇳 Beijing Fule Science & Technology Development Co., Ltd. China

> Fule Interbody Fusion Cage System

China's Beijing Fule Science & Technology Development Co., Ltd. has secured 510(k) clearance for its Fule Interbody Fusion Cage System for use in spinal surgery.

> **Intelligence:** A second clearance for this company in a short time, this one for a spinal fusion cage, indicates a deliberate strategy to build a comprehensive orthopedic implant portfolio for the US market.

🇨🇳 Zdeer Technology (Henan) Co., Ltd. China

> Bone Conduction Hearing Aid (G41157, G41158, G41159, G41160, G42151, G42152, G42153, G42154, G42155, G42156, G42157, G42158, G42159, G42160, G43151, G43152, G43153, G43154, G43155, G43156, G45151, G45152, G45153, G45154, G45155, G45156, G45157, G45158, G45159, G45160, G46151, G46152, G46153, G46154, G46155, G46156, G46157, G46158)

Zdeer Technology (Henan) Co., Ltd. of China has received 510(k) clearance for a wide range of bone conduction hearing aid models.

> **Intelligence:** Following its clearance for a hair growth device, this move into bone conduction hearing aids suggests Zdeer is pursuing a multi-pronged strategy to enter various US consumer health-tech segments.

🇨🇳 SteriLance Medical (Suzhou), Inc. China

> Disposable Blood Lancet (Soft)

China's SteriLance Medical (Suzhou), Inc. has obtained 510(k) clearance for its disposable soft blood lancet for capillary blood sampling.

> **Intelligence:** This clearance for a high-volume disposable used in blood sampling positions the company to compete as a supplier for the US diagnostics and diabetes care markets.

🇯🇵 Whill, Inc. Japan

WHILL (WHILL Model C2)

Japanese firm Whill, Inc. has received 510(k) clearance for its WHILL Model C2, a personal electric mobility vehicle.

Intelligence: This clearance for a new model helps Japanese innovator Whill, Inc. to strengthen its brand and product lineup in the US market for advanced, design-focused personal mobility devices.

🇨🇳 Sanhe LEFIS Electronics Co., Ltd. China

Intense Pulsed Light Therapy Device

Sanhe LEFIS Electronics Co., Ltd. from China has gained 510(k) clearance for its Intense Pulsed Light (IPL) Therapy Device for hair removal.

Intelligence: This clearance allows the company to enter the US aesthetic device market for applications like hair removal, a segment with numerous established competitors.

🇰🇷 Lg Electronics.Inc South Korea

Medical Monitor (40HT513D)

South Korea's LG Electronics Inc. has secured 510(k) clearance for its 40HT513D medical monitor for displaying medical images.

Intelligence: For a major electronics conglomerate like LG, securing 510(k) clearance for medical-grade monitors is a key step to legitimize its B2B healthcare division and compete for large hospital and imaging center contracts in the US.

🇨🇳 Polybell (Guangzhou) Limited China

Electric Breast Pump (BH627, BH628, BH707, BH709, BH813, BH816, BH110, H701, H1129, H1128, H620, H705, H706)

China's Polybell (Guangzhou) Limited received 510(k) clearance for a wide variety of its electric breast pump models.

Intelligence: The clearance for a large number of breast pump models suggests a strategy to serve as a versatile supplier or original equipment manufacturer (OEM) for different brands in the US market.

🇰🇷 Dyne Medical Group, Inc. South Korea

DYNE PORT

Dyne Medical Group, Inc. of South Korea has obtained 510(k) clearance for its DYNE PORT, an implantable vascular access port.

Intelligence: This clearance for an implantable port could allow the Korean company to enter the US market for long-term vascular access, a critical component in oncology and chronic disease management.

🇹🇼 Avita Corporation Taiwan

AViTA Breast Pump

Taiwan's Avita Corporation has received 510(k) clearance for its AViTA electric breast pump.

Intelligence: This clearance provides another option from a Taiwanese manufacturer in the competitive US market for electric breast pumps.

🇨🇳 Nagy Oral Technology Qinhuangdao Co., Ltd. China

Fluoride Varnish (Type A,Type C)

Nagy Oral Technology Qinhuangdao Co., Ltd. from China has secured 510(k) clearance for its fluoride varnish, a dental caries preventative agent.

Intelligence: Gaining clearance for a preventative dental consumable like fluoride varnish allows the company to target a recurring revenue stream from dental practices across the US.

🇨🇳 Changzhou Boen Zhongding Medical Technology Co., Ltd. China

Dental X-ray System

China's Changzhou Boen Zhongding Medical Technology Co., Ltd. has gained 510(k) clearance for its intraoral dental X-ray system.

Intelligence: This clearance positions another Chinese manufacturer to compete in the US dental capital equipment market, likely targeting private practices with a focus on value.

🇰🇷 Hass Corp. South Korea

> Rosetta SM, Rosetta SP

Hass Corp. of South Korea has received 510(k) clearance for its Rosetta SM and Rosetta SP, which are lithium silicate glass ceramic blocks for dental restorations.

> **Intelligence:** The clearance of new dental ceramic materials allows Korea's Hass Corp. to expand its portfolio for US dental labs and clinicians, reinforcing its position in the aesthetic dental materials segment.

🇯🇵 Hitachi High-Tech Corp. Japan

> PROBEAT-CR

Japan's Hitachi High-Tech Corp. has obtained 510(k) clearance for its PROBEAT-CR, a system for proton beam therapy.

> **Intelligence:** This clearance for its PROBEAT system reinforces Hitachi's significant position in the highly specialized, high-cost US market for proton beam therapy equipment.

🇨🇳 Shenzhen Magnet Technology Co., Ltd. China

> Bone Conduction Hearing Aid (XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3)

Shenzhen Magnet Technology Co., Ltd. from China has secured 510(k) clearance for its bone conduction hearing aids.

> **Intelligence:** This clearance marks another entry from a Chinese manufacturer into the niche but growing US market for bone conduction hearing solutions, an alternative to traditional hearing aids.

🇨🇳 Xiamen Weiyou Intelligent Technology Co., Ltd. China

> Cryo And Thermo Therapy System

China's Xiamen Weiyou Intelligent Technology Co., Ltd. received 510(k) clearance for its Cryo and Thermo Therapy System, which provides cold and heat therapy.

> **Intelligence:** This clearance positions the company to compete in the US physical therapy and sports medicine markets with a device offering combined cooling and heating therapy.

🇹🇼 Alpha Intelligence Manifolds, Inc. Taiwan

DeepXray Spina

Alpha Intelligence Manifolds, Inc., a Taiwanese company, has gained 510(k) clearance for DeepXray Spina, an AI-powered software for analyzing spinal X-rays.

Intelligence: This clearance for an AI-powered diagnostic tool highlights the strategy of Taiwanese firms to develop and export specialized medical software, moving up the value chain beyond hardware manufacturing.

🇹🇼 Tech-Image CO., LTD. Taiwan

“Tech-Image” Video Endoscope System

🇯🇵 MicroVention, Inc., d/b/a Terumo Neuro Japan

BOBBY Balloon Guide Catheter

MicroVention, Inc., the US-based neurovascular entity of Japan's Terumo, received 510(k) clearance for its BOBBY Balloon Guide Catheter used in ischemic stroke procedures.

Intelligence: As a US-based entity of Japan's Terumo, this clearance for a novel balloon guide catheter strengthens its neurovascular portfolio, supporting its competitive standing in the US stroke intervention market.

🇨🇳 Shenzhen TPH Technology Co., Ltd. China

Mother's Nature W1 Warming Wearable Breast Pump

China's Shenzhen TPH Technology Co., Ltd. has secured 510(k) clearance for its Mother's Nature W1, a wearable breast pump that includes a warming feature.

Intelligence: The addition of a 'warming' feature suggests Chinese manufacturers are now competing not just on price but also on differentiated features in the crowded US wearable breast pump market.

🇰🇷 Sejong Medical Co., Ltd. South Korea

LAP-iX2N

Sejong Medical Co., Ltd. of South Korea has received 510(k) clearance for its LAP-iX2N, a disposable laparoscopic instrument.

Intelligence: This clearance for a laparoscopic instrument allows the Korean company to expand its offerings for the minimally invasive surgery market in the US.

🇹🇼 Chanpin Medtak Co., Ltd. Taiwan

> ChanPin Pedicle Screw Spinal System

Taiwan's Chanpin Medtak Co., Ltd. has gained 510(k) clearance for its ChanPin Pedicle Screw Spinal System for posterior spinal fixation.

> **Intelligence:** This clearance adds another Taiwanese supplier to the competitive US spinal hardware market, broadening the options available to surgeons and hospitals.

🇰🇷 Weero Co., Ltd. South Korea

> Apollo Quattro (APQ-10M)

Weero Co., Ltd., a South Korean company, has obtained 510(k) clearance for its Apollo Quattro, a dental X-ray system.

> **Intelligence:** This clearance for a dental imaging system could help Weero Co. establish a foothold in the US dental equipment market, competing with numerous established brands.

🇨🇳 Jiangsu Intco Medical Products Co., Ltd. China

> Virgo Mobility Scooter (Virgo-D,Virgo-F)

China's Jiangsu Intco Medical Products Co., Ltd. has received 510(k) clearance for its Virgo Mobility Scooter models.

> **Intelligence:** For a major medical consumables manufacturer like Intco, this clearance represents a continued diversification into the durable medical equipment (DME) and mobility sector for the US market.

🇨🇳 Unimed Medical Supplies, Inc. China

> Temperature probes (T2252-PG); Temperature probes (TCMA-AG); Temperature probes (TCMA-PG); Temperature probes (TMQ-DAG); Temperature probes (THP-DAG)

China's Unimed Medical Supplies, Inc. has secured 510(k) clearance for a series of reusable and disposable temperature probes for patient monitoring.

> **Intelligence:** Gaining clearance for a range of compatible temperature probes positions the company as a potential third-party supplier for various patient monitoring systems used in US hospitals.

🇨🇳 Hangzhou Qiantang Longyue Biotechnology Co., Ltd. China

Vial Adapter

Hangzhou Qiantang Longyue Biotechnology Co., Ltd. from China has gained 510(k) clearance for its Vial Adapter, used for transferring drugs from a vial.

Intelligence: This clearance for a drug delivery component like a vial adapter allows the company to supply the US pharmaceutical and hospital pharmacy markets.

🇨🇳 Zhejiang Innuovo Rehabilitation Devices Co.,Ltd China

Power Wheelchair (N5515A, N5516, N5517A, N5519)

China's Zhejiang Innuovo Rehabilitation Devices Co., Ltd. has received another 510(k) clearance for a new series of its power wheelchairs.

Intelligence: A second power wheelchair clearance for this company within a short timeframe demonstrates a strategy to build a broad portfolio of mobility products for the US market.

🇨🇳 Beijing Sano Laser S&T Development Co.,Ltd China

LumiGlam Laser System (SHE-LSP601-3)

Beijing Sano Laser S&T Development Co., Ltd. of China has obtained 510(k) clearance for its LumiGlam Laser System for hair removal and wrinkle reduction.

Intelligence: This clearance allows the company to compete in the US market for aesthetic laser systems used in dermatology clinics and medical spas.

🇰🇷 Uzinmedicare Co., Ltd. South Korea

Spectra Platinum Mini

South Korea's Uzinmedicare Co., Ltd. has received 510(k) clearance for its Spectra Platinum Mini, a portable electric breast pump.

Intelligence: The clearance of a 'Mini' model suggests the Korean company is targeting the portable breast pump segment in the US, competing on convenience and size.

🇨🇳 Yofo Medical Technology Co., Ltd. China

> Dental Cone Beam Computed Tomography System

China's Yofo Medical Technology Co., Ltd. has secured 510(k) clearance for its Dental Cone Beam Computed Tomography (CBCT) System.

> **Intelligence:** This clearance for an advanced dental imaging system (CBCT) signals that Chinese manufacturers are moving into more sophisticated and higher-cost capital equipment for the US dental market.

🇨🇳 Keya Medical Technology Co., Ltd. China

> DEEPVESSEL Plaque

Keya Medical Technology Co., Ltd. from China has gained 510(k) clearance for DEEPVESSEL Plaque, an AI software that analyzes coronary plaque from CT scans.

> **Intelligence:** This clearance for a cardiovascular AI diagnostic tool marks a significant step for the Chinese company, positioning it to enter the high-stakes US market for advanced clinical decision support software.

💊 Drug Approvals

2 new drug approvals this week (1 NMEs). 10 efficacy supplements. 12 generics (ANDA).

New Drug Approvals (NDA / BLA)

VELIGROTUG LUMVOA **NME** VIRIDIAN THERAPEUTICS INC

WHAT IT IS

Novel anti-CD19 monoclonal antibody administered via subcutaneous injection.

WHY IT MATTERS

As a New Molecular Entity, this approval is a pivotal event for Viridian Therapeutics, potentially validating its platform and transforming the company from a clinical-stage to a commercial-stage organization.

FOSAPREPITANT NAVITRUX **New Formulation** AVYXA HOLDINGS

WHAT IT IS

Substance P/NK1 receptor antagonist; new oral formulation of an existing IV therapy.

WHY IT MATTERS

This approval introduces a new branded version of fosaprepitant into a market with established generic competition, suggesting Avyxa's strategy will likely rely on a differentiated formulation or a competitive pricing model to capture share.

New Indications (Efficacy Supplements)

RISANKIZUMAB-RZAA SKYRIZI **New Formulation** ABBVIE INC

WHAT IT IS

Risankizumab-rzaa is an IL-23 inhibitor monoclonal antibody administered via subcutaneous injection.

Adults with moderately to severely active Crohn's disease.

WHY IT MATTERS

This approval in ulcerative colitis directly challenges established IBD therapies and is a key part of AbbVie's strategy to build its post-Humira immunology franchise. It positions Skyrizi to capture share from competitors like Stelara, which is nearing its loss of exclusivity.

VIMSELTINIB ROMVIMZA New Formulation DECIPHERA PHARMS

WHAT IT IS

Vimsertinib is an oral KIT and PDGFRα inhibitor, a novel tyrosine kinase inhibitor.

WHY IT MATTERS

As a second-to-market therapy for TGCT, vimseltinib's potentially favorable safety profile compared to the incumbent could allow it to become the new standard of care. This approval is a major validation for Deciphera's pipeline and commercial strategy.

INCOBOTULINUMTOXINA XEOMIN New Formulation MERZ PHARMS

WHAT IT IS

IncobotulinumtoxinA is a botulinum neurotoxin type A that inhibits acetylcholine release, administered via intramuscular injection.

Pediatric patients aged 2 years and older with chronic sialorrhea.

WHY IT MATTERS

In the increasingly crowded neurotoxin market, this label expansion is a tactical move by Merz to defend Xeomin's market share. Each new indication could help reinforce its position against both legacy and newer long-acting competitors.

OLEZARSEN SODIUM TRYNGOLZA New Formulation Priority Review

IONIS PHARMS INC

WHAT IT IS

Olezarsen sodium is a first-in-class apoC-III antisense oligonucleotide administered via subcutaneous injection, with FDA Priority Review.

WHY IT MATTERS

This approval represents a classic lifecycle management strategy, introducing a next-generation therapy with an improved safety profile that is expected to replace Ionis's own older drug. It also serves to further validate the company's proprietary LICA technology platform.

PALBOCICLIB IBRANCE New Formulation PFIZER

WHAT IT IS

Palbociclib is an oral CDK4/6 inhibitor, a targeted therapy.

WHY IT MATTERS

This label update appears to be a defensive maneuver by Pfizer to protect Ibrance's market share in the highly competitive CDK4/6 inhibitor class. Such incremental improvements may help mitigate erosion from rivals that have demonstrated superior overall survival data.

PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH KEYTRUDA QLEX

New Formulation

MERCK SHARP DOHME

WHAT IT IS

This combination is a PD-1 inhibitor with a recombinant hyaluronidase, offering a new subcutaneous injection formulation.

WHY IT MATTERS

The approval of a subcutaneous formulation is the cornerstone of Merck's strategy to defend its largest franchise from biosimilar erosion post-2028. This more convenient option is designed to facilitate a large-scale patient switch, aiming to preserve significant revenue.

PALBOCICLIB IBRANCE New Formulation

PFIZER

WHAT IT IS

Palbociclib is an oral CDK4/6 inhibitor, a targeted therapy.

WHY IT MATTERS

With competitors Verzenio and Kisqali gaining momentum, any label enhancement for Ibrance is a necessary attempt to reinforce its value proposition to prescribers. This move could help Pfizer defend its position in an increasingly data-driven and competitive market.

PEMBROLIZUMAB KEYTRUDA New Formulation

MERCK SHARP DOHME

WHAT IT IS

Pembrolizumab is a PD-1 inhibitor monoclonal antibody administered via IV infusion.

Adjuvant treatment for stage IIB or IIC melanoma following complete resection.

WHY IT MATTERS

Each new indication for intravenous Keytruda further cements its status as a foundational immuno-oncology therapy across a vast range of cancers. This relentless label expansion strategy is crucial for maximizing revenue before its primary patents expire.

SACITUZUMAB GOVITECAN TRODELVY New Formulation

IMMUNOMEDICS INC

WHAT IT IS

Sacituzumab govitecan is a Trop-2-directed antibody-drug conjugate administered via IV infusion.

HR-positive, HER2-negative metastatic breast cancer after prior endocrine and systemic therapies.

WHY IT MATTERS

Expanding into the large HR+/HER2- breast cancer population is critical for Gilead to justify its acquisition of Immunomedics and build a major oncology franchise. This approval sets up a direct competitive battle with AstraZeneca and Daiichi Sankyo's Enhertu.

SACITUZUMAB GOVITECAN TRODELVY New Formulation IMMUNOMEDICS INC

WHAT IT IS

Sacituzumab govitecan is a Trop-2-directed antibody-drug conjugate administered via IV infusion.

HR-positive, HER2-negative metastatic breast cancer after prior endocrine and systemic therapies.

WHY IT MATTERS

This approval significantly broadens Trodelvy's addressable market and is expected to establish it as a key pillar of Gilead's oncology portfolio. The success in a new tumor type could also bolster confidence in the broader potential of its TROP-2 ADC platform.

🩺 Medical Devices

510(k) clearances: **197** | PMA Original: **4** | Panel-Track: **1** | 30-Day Notice: **64**

PMA Approvals

HepQuant SHUNT® Liver Diagnostic Test

Hepquant, LLC

> Liver diagnostic test for assessing liver function and detecting portosystemic shunting.

VENTANA PTEN (SP218) RxDx Assay

Ventana Medical Systems, Inc. (Roche Tissue Diagnostics)

> In vitro diagnostic assay for detecting PTEN protein expression to guide cancer treatment.

saypha® ChiQ™

Croma-Pharma GmbH

> Dermal filler, an injectable hyaluronic acid product for aesthetic skin treatment.

AbsorbaSeal 5.6.7F Vascular Closure Device

Cyndrx, LLC

> Vascular closure device for sealing arterial or venous punctures after catheterization procedures.

SKINVIVE by JUVEDERM®

Allergan

> Dermal filler, an injectable hyaluronic acid product for improving skin smoothness and hydration.

510(k) Clearances (most recent 10)

Device	Applicant	Date
Dynamis Robotic Surgical System Robotic surgical system for assisting surgeons in performing complex medical procedures.	LEM Surgical AG	2026-06-20
InstaTRU Instant Biological Indicator for Steam (IBI-05) Biological indicator for monitoring the effectiveness of steam sterilization processes in healthcare settings.	True Indicating, LLC	2026-06-18
SteriBest® Sterilization Tray System Sterilization tray system for organizing and protecting surgical instruments during sterilization and storage.	Mastel Surgical	2026-06-18

SmartSpectra Vital Signs Monitor 1.0 Vital signs monitor for non-invasively measuring and displaying patient physiological parameters.	Presage Security, Inc. d/b/a Presage Technologies, Inc.	2026-06-18
ARTHUR Medical device — Robotic surgical system for assisting in various surgical procedures.	ROPCA ApS	2026-06-18
Pelvic Muscle Trainer (KM510, KM516B) Pelvic muscle trainer for strengthening pelvic floor muscles to treat incontinence and improve pelvic health.	Shenzhen Konmed Technology Co., Ltd.	2026-06-18
MegaGen Zygoma Dental Implant System Dental implant system for anchoring prosthetic teeth in patients with significant jawbone loss.	Megagen Implant Co., Ltd.	2026-06-18
AND Medical Femoral Nail System (PFNA01); AND Medical Femoral Nail System (PFNA02) Orthopedic femoral nail system for stabilizing fractures of the femur (thigh bone).	Suzhou and Science & Technology Development Corp.	2026-06-18
Precice™ Max System and Precice™ Ankle Salvage System Orthopedic intramedullary nail system for limb lengthening and bone deformity correction.	NuVasive Specialized Orthopedics	2026-06-18
Implantmed Plus II & Piezomed Plus II Module Dental surgical unit for performing implantology and piezosurgical procedures in dentistry.	W&H Dentalwerk Buermoos GmbH	2026-06-18

* Full 197-item 510(k) dataset available in the Excel file attached to this issue.

⚠️ Warning Letters

Total this week: **4** | Significant (manufacturing/GMP): **4** | Unapproved/labeling: **0**

Excelvision - Fareva (CDER)

> The company failed to adhere to current good manufacturing practices for finished pharmaceuticals, rendering their products adulterated.

Wizcure Pharmaa Private Limited (CDER)

> Deficiencies in current good manufacturing practices for finished drug products led to the drugs being considered adulterated.

Genzyme Ireland Limited (CBER)

> The firm exhibited deviations from current good manufacturing practices concerning its Biologics License Application.

Yangzhou Hongshengding Chemical Co., Ltd. (CDER)

> The company refused to permit access to and copying of required records during an inspection.

🔴 Drug Recalls

Product	Reason	Class
DHP Topical Anesthetic Gel, Benzocaine 20%, Strawb	Defective container:may contain bottles with incomplete seals	Class II
Med Pride, HYDROCORTISONE CREAM 1%, Net Wt. 1 oz (	CGMP Deviations; deficiencies observed during FDA inspection	Class II
PureLife, TOPICAL ANESTHETIC GEL, BENZOCAINE 20%,	Defective container:may contain bottles with incomplete seals	Class II
Rapidol, Triple Antibiotic First Aid Ointment, Bac	CGMP Deviations; deficiencies observed during FDA inspection	Class II
Med Pride, Triple Antibiotic Ointment, Bacitracin	CGMP Deviations; deficiencies observed during FDA inspection	Class II
Lucky Super Soft, First Aid Triple Antibiotic Oint	CGMP Deviations; deficiencies observed during FDA inspection	Class II
Med Pride, Bacitracin Zinc Ointment, 1oz (28.3g) p	CGMP Deviations; deficiencies observed during FDA inspection	Class II
Vasopressin 2 Units/2 mL in 0.9% Sodium Chloride,	Subpotent Drug	Class II
Chlorthalidone Tablets, USP, 25 mg, [100 or 1000]	Failed Dissolution Specifications	Class II
Quala Dental Products, Topical Anesthetic Gel, 20	Defective container:may contain bottles with incomplete seals	Class II

📋 FDA Guidance & Regulatory Actions

8 FDA regulatory documents this week.

Endo Operations Limited, et al.; Withdrawal of Approval of 34 New Drug Applications (2026-07-06 • Notice)

This Notice announces the withdrawal of approval for 34 New Drug Applications (NDAs) from Endo Operations Limited and other manufacturers. It affects pharmaceutical companies with these specific approved drug products.

Expedited Investigational New Drug Pilot Program; Request for Information; Correction (2026-07-06 • Notice)

This Notice is a correction to a request for information on the Expedited Investigational New Drug Pilot Program. It affects pharmaceutical companies and researchers interested in expedited drug development pathways.

Determination That VASOPRESSIN IN SODIUM CHLORIDE (vasopressin) 0.9%, Injection, 50 units/50 milliliters (1 unit/milliliters) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-07-06 • Notice)

This Notice announces the determination that VASOPRESSIN IN SODIUM CHLORIDE was not withdrawn for safety or effectiveness reasons. It affects generic drug manufacturers seeking to market a generic version of this drug.

Medical Devices; Anesthesiology Devices; Classification of the Monitor for Opioid Induced Impairment of Oxygenation (2026-06-30 • Rule)

This final rule classifies the Monitor for Opioid Induced Impairment of Oxygenation as an anesthesiology medical device. It affects manufacturers developing or marketing such monitoring devices.

Medical Devices; General and Plastic Surgery Devices; Classification of the Skin Patch for Treatment of Hyperhidrosis (2026-06-30 • Rule)

This final rule classifies the Skin Patch for Treatment of Hyperhidrosis as a general and plastic surgery medical device. It affects manufacturers developing or marketing such skin patches.

Medical Devices; Orthopedic Devices; Classification of the Medial Knee Implanted Shock Absorber (2026-06-29 • Rule)

This final rule classifies the Medial Knee Implanted Shock Absorber as an orthopedic medical device. It affects manufacturers developing or marketing such knee implants.

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-Biologics License Application (BLA) 125842 From Capricor, Inc. for Deramiocel (Human Allogeneic Cardiosphere-Derived Cells) (2026-06-29 • Notice)

This Notice announces a public meeting and requests comments on Biologics License Application (BLA) 125842 for Deramiocel from Capricor, Inc. It affects the biologics industry and stakeholders

interested in cellular and gene therapies.

Determination of Regulatory Review Period for Purposes of Patent Extension; VYALEV (2026-06-29 • Notice)

This Notice announces the determination of the regulatory review period for VYALEV for patent extension purposes. It affects the pharmaceutical manufacturer of VYALEV and other drug companies seeking patent term extensions.

FDA Weekly Intelligence

Data sources: openFDA • Federal Register • FDA.gov official publications

Auto-generated • 2026-07-04 10:07 UTC

📜 Terms of Use & Disclaimer (Individual Plan)

Thank you for subscribing to **FDA Weekly Intelligence**. Please read the following terms carefully before using this report and any accompanying files.

1. Data Sources & AI-Assisted Generation

All data and information published in this report is sourced from official U.S. government publications, including the U.S. Food and Drug Administration (FDA) official website, the Federal Register, and the openFDA database.

To extract timely and actionable intelligence from large volumes of regulatory data, this report uses advanced generative AI (large language models) for data processing, summarization, and strategic commentary generation.

2. Accuracy & AI Hallucination Disclaimer

While we apply quality review processes after AI-assisted generation to minimize errors, the nature of machine learning models means that translation nuances, contextual misinterpretations, or inaccuracies may occasionally appear. We do not guarantee the 100% accuracy, completeness, timeliness, or fitness for a particular purpose of any information provided.

For decisions requiring verified regulatory information, always refer to the original English-language source documents published by the FDA.

3. No Professional Advice

This report provides general market intelligence for informational purposes only. It does not constitute and should not be relied upon as:

- **Regulatory or legal advice:** Not a substitute for qualified legal or regulatory counsel regarding FDA submissions, compliance, or enforcement matters.
- **Investment advice:** Not a recommendation to buy, sell, or hold any security, or to pursue any M&A or licensing transaction.
- **Medical advice:** Not intended to guide clinical decisions by healthcare professionals or patients.
- **Drug or device recommendation:** This report summarizes FDA's publicly announced approvals, clearances, warning letters, and other enforcement actions. It does not recommend, endorse, or make any representation regarding the efficacy, safety, or superiority of any specific drug or medical device.

The publisher accepts no liability for any direct or indirect loss, including lost profits, business interruption, or consequential damages, arising from reliance on the information in this report. All decisions based on this report are made at the reader's own risk.

4. Copyright, Permitted Use & Sharing Policy (Individual Plan)

All intellectual property rights in this report and accompanying data files are owned by the publisher. To protect the value of this service, the following usage rules apply:

Permitted Use (Individual Subscriber)
Access to this report is granted solely to the registered individual subscriber. You may use data and insights from this report in your own professional work, including internal presentations, memos, and reports, provided you do not reproduce the report in its entirety.

Prohibited Use (Sharing & Redistribution)
Forwarding or distributing this report (HTML, PDF, or Excel) to colleagues, clients, or any third party is strictly prohibited. Sharing login credentials or account access with others is also prohibited. Publishing any portion on websites or social media, or reselling this content, is not permitted. Violations may result in immediate termination of service and claims for damages.

5. Subscription, Auto-Renewal & Refund Policy

Subscription & Auto-Renewal Disclosure: This is a recurring subscription service. Your subscription will automatically renew at the end of each billing period, and your payment method will be charged automatically unless you cancel before the renewal date. You will receive a reminder email prior to each renewal. To cancel, log in to your Gumroad or Substack account and cancel before the next billing date. Cancellation stops future charges but does not entitle you to a refund for the current period.

Refund Policy: Due to the digital nature of this product, refunds are not available once a report has been delivered or a billing period has commenced. If you believe you were charged in error, please contact us within 7 days at info@troy-technical.jp and we will review your case.

6. Privacy & GDPR Compliance

We collect and process only the personal data necessary to deliver this service (name, email address, and billing information). Your data is processed by our payment and delivery platforms (Gumroad and/or Substack) in accordance with their respective privacy policies. We do not sell or share your personal data with third parties for marketing purposes.

If you are a resident of the European Economic Area (EEA) or the United Kingdom, you have the following rights under the General Data Protection Regulation (GDPR) and applicable UK data protection law:

- **Right of access:** You may request a copy of the personal data we hold about you.
- **Right to rectification:** You may request correction of inaccurate personal data.
- **Right to erasure:** You may request deletion of your personal data, subject to our legal obligations to retain certain records.
- **Right to object / restrict processing:** You may object to or request restriction of processing of your personal data in certain circumstances.
- **Right to data portability:** You may request a machine-readable copy of your data.

To exercise any of these rights, please contact us at info@troy-technical.jp. We will respond within 30 days. You also have the right to lodge a complaint with your local data protection authority.

The legal basis for processing your personal data is the performance of a contract (delivery of the subscription service you have purchased).

7. Limitation of Liability

To the maximum extent permitted by applicable law, the publisher's total liability to you for any claim arising out of or in connection with this service shall not exceed the total subscription fees paid by you in the three (3) months preceding the claim. In no event shall the publisher be liable for any indirect, incidental, special, consequential, or punitive damages, including but not limited to loss of profits, loss of data, or business interruption, even if advised of the possibility of such damages.

8. Dispute Resolution & Governing Law

These Terms are governed by the laws of Japan, without regard to its conflict of law provisions. Any dispute, controversy, or claim arising out of or relating to these Terms or the service shall first be attempted to be resolved through good-faith negotiation. If not resolved within 30 days, the dispute shall be finally settled by binding arbitration administered by the Japan Commercial Arbitration Association (JCAA) under its Commercial Arbitration Rules. The arbitration shall be conducted in English, in Tokyo, Japan. The arbitral award shall be final and binding on both parties.

Nothing in this section shall prevent either party from seeking urgent injunctive or other equitable relief from a court of competent jurisdiction to prevent irreparable harm.

9. Service Continuity Statement

The core functionality of this service relies heavily on third-party generative AI (large language model) services. If the supply policies, pricing structure, or terms of use of such third-party services change materially, or if such services are discontinued or become unavailable, such that the quality, cost structure, or operation of this service can no longer be reasonably maintained, the publisher reserves the right to **suspend or terminate this service**. If termination becomes necessary, subscribers will be notified by email at least 30 days in advance, and any fees already collected for undelivered subscription periods will be refunded on a pro-rata basis. The publisher will use reasonable efforts to maintain service stability but does not guarantee that this service will continue indefinitely.

10. Changes to These Terms

We reserve the right to update these Terms at any time. Material changes will be notified to subscribers by email at least 14 days before taking effect. Continued use of the service after the effective date of any changes constitutes your acceptance of the revised Terms.

 / Publisher: Troy Technical / Last updated: June 28, 2026 / Contact: info@troy-technical.jp