FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 27, 2026

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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 was defined less by new drug approvals and more by significant market expansion for existing therapies, with a remarkable ten efficacy supplements granted. This focus on label expansion was set against a backdrop of heightened enforcement, as four significant Warning Letters signal continued scrutiny on quality and compliance. Most strategically, a high volume of interactions involving Asian companies highlights their accelerating integration into the US market, a critical competitive and partnership trend for Western firms to monitor.

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 received 510(k) clearance for its Pelvic Muscle Trainer, a device intended for strengthening pelvic floor muscles.

> **Intelligence:** This clearance allows the Chinese company to enter the growing US consumer 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. obtained 510(k) clearance for its MegaGen Zygoma Dental Implant System, used for dental rehabilitation in patients with atrophic maxilla.

> **Intelligence:** Securing clearance for a specialized zygomatic implant system may allow Megagen to compete for more complex, high-value dental implant cases in the US market.

🇨🇳 Suzhou and Science & Technology Development Corp. China

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

Suzhou and Science & Technology Development Corp. of China received 510(k) clearance for its AND Medical Femoral Nail System, an orthopedic implant for treating femur fractures.

> **Intelligence:** This entry into the US orthopedic trauma segment positions the company to compete in a market often characterized by high-volume, price-sensitive purchasing by hospital systems.

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

> Portable DR Imaging System

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

> **Intelligence:** The clearance of a portable DR system suggests a strategy to target point-of-care or mobile imaging applications in the US, a segment with distinct needs from fixed, in-hospital systems.

🇯🇵 FUJIFILM Healthcare Americas Corporation Japan

Synapse PACS (7.6.0)

The US subsidiary of Japan's Fujifilm Group, FUJIFILM Healthcare Americas Corporation, received 510(k) clearance for an updated version of its Synapse Picture Archiving and Communication System (PACS) software.

Intelligence: Continuous updates to its core Synapse informatics platform are critical for Fujifilm to maintain interoperability and strengthen the value proposition of its broader imaging hardware portfolio in the US.

🇨🇳 Zhejiang Innuovo Rehabilitation Devices Co.,Ltd China

Power Wheelchair (W5915B, W5915C, W5915D)

Zhejiang Innuovo Rehabilitation Devices Co., Ltd. from China obtained 510(k) clearance for several models of its power wheelchair.

Intelligence: This clearance broadens the Chinese manufacturer's portfolio of cleared mobility devices for the US market, potentially enabling it to serve a wider range of patient needs.

🇰🇷 GC America, Inc. South Korea

SRGC-06

GC America, Inc., the US entity of a South Korean parent company, received 510(k) clearance for the SRGC-06, a chairside CAD/CAM milling machine for dental restorations.

Intelligence: By offering a chairside milling machine, GC America can better support dentists adopting digital workflows, potentially increasing the pull-through of its own restorative materials.

🇰🇷 Vieworks Co., Ltd. South Korea

VIVIX-S 4386W (FXRD-4386WA)

South Korea's Vieworks Co., Ltd. has received 510(k) clearance for its VIVIX-S 4386W, a flat panel digital radiography detector.

Intelligence: This latest clearance adds another model to Vieworks' extensive portfolio of digital X-ray detectors, reinforcing its position as a key component supplier for 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. secured 510(k) clearance for its Hemolase Fiber, a sterile, disposable laser fiber for surgical applications.

> **Intelligence:** This clearance for a disposable surgical accessory provides the company with a potential entry into the US market for high-volume, recurring revenue consumables used with surgical laser systems.

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

> Curing Light (M-Cure 6)

Guangzhou Rebornendo Medical Instrument Co., Ltd. from China received 510(k) clearance for its M-Cure 6, a dental curing light used to polymerize light-cured restorative materials.

> **Intelligence:** Entering the US market with a fundamental dental tool like a curing light could serve as a foundational step for the company to build brand recognition and distribution channels for future products.

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

> Wrist Blood Pressure Monitor (XW-05)

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

> **Intelligence:** This clearance positions the company to compete in the large US over-the-counter and direct-to-consumer market for home 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:** The clearance of this wearable breast pump under the Momcozy brand signals a direct-to-consumer strategy targeting the US market for modern, convenient mother and baby care products.

🇨🇳 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. secured 510(k) clearance for its LED Light Therapy Mask, intended for treating mild to moderate acne.

Intelligence: This clearance allows the company to tap into the rapidly growing US market for at-home aesthetic and dermatological devices, a segment that blends consumer electronics with medical technology.

🇹🇼 Oneness Biotech Co., Ltd. Taiwan

Bonvadis®

Oneness Biotech Co., Ltd. from Taiwan received 510(k) clearance for Bonvadis®, a cream intended for the management of diabetic foot ulcers and other wounds.

Intelligence: For Oneness Biotech, primarily a drug development company, this device clearance in the advanced wound care space could provide a source of commercial revenue in the US while its pharmaceutical pipeline matures.

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

Assisted Reproduction Laser System (Model ILS-400M)

China's Hua Yue Medical Technology Co., Ltd. obtained 510(k) clearance for its Assisted Reproduction Laser System, used for procedures in assisted reproductive technology (ART) labs.

Intelligence: This clearance for specialized capital equipment positions the company to target the growing number of fertility clinics and ART laboratories in the United States.

🇹🇼 Socko Medical Co., Ltd. Taiwan

“Socko” Vimax Spinal Fixation System

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

Non-Sterile Ultrasound Gel Sterile Ultrasound Gel

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

Intelligence: By securing clearance for both sterile and non-sterile gels, the company can address different clinical needs, from routine diagnostics to interventional procedures, potentially broadening its customer base in the US.

🇨🇳 Honsun (Nantong) Co., Ltd. China

Portable Oxygen Concentrator

China's Honsun (Nantong) Co., Ltd. obtained 510(k) clearance for its Portable Oxygen Concentrator, a device that provides supplemental oxygen to patients.

Intelligence: This clearance allows Honsun to compete in the US home healthcare equipment market, which has seen increased demand for portable and patient-friendly respiratory devices.

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

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

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

Intelligence: Securing another clearance for a new breast pump model suggests the company is pursuing a rapid product iteration and portfolio expansion strategy to capture different feature and price segments of 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. of China obtained 510(k) clearance for its Fule Metallic Lockable Intramedullary Nail Systems for fracture fixation.

Intelligence: This clearance marks an entry for the Chinese company into the competitive US orthopedic trauma device market.

🇹🇼 Hivox Biotek, Inc. Taiwan

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

Taiwan's Hivox Biotek, Inc. received 510(k) clearance for its TENS/EMS device, which provides electrical stimulation for pain relief and muscle stimulation.

Intelligence: This clearance allows Hivox Biotek to address the US over-the-counter market for non-pharmacological pain management solutions, a segment driven by consumer demand for alternatives to medication.

🇨🇳 Hunan Ruijiong Biotech Co., Ltd. China

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

Hunan Ruijiong Biotech Co., Ltd. from China secured 510(k) clearance for its KT Airway Clearance Device II, designed to dislodge mucus in patients with respiratory conditions.

> **Intelligence:** This clearance positions the company to enter the US market for respiratory care, potentially targeting both home-use and clinical settings for patients with chronic lung diseases.

🇨🇳 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)

China's Hubei Yjt Technology Co., Ltd. obtained 510(k) clearance for its Laser Hair Growth System, a low-level laser therapy device for treating androgenetic alopecia.

> **Intelligence:** The clearance of multiple models with varying laser counts suggests a strategy to offer a tiered product line for the US at-home aesthetic device market, targeting different consumer price points.

🇯🇵 Fujifilm Corporation Japan

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

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

> **Intelligence:** Expanding its portfolio of specialized endoscopes could strengthen Fujifilm's competitive position against other major players in the US pulmonology and GI device markets.

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

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

Zdeer Technology (Henan) Co., Ltd. from China secured 510(k) clearance for its Laser Hair Growth Device, intended for the treatment of hair loss.

> **Intelligence:** This clearance marks another entry from a Chinese manufacturer into the competitive US consumer market for light-based aesthetic and hair restoration therapies.

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

HERA Interlocking Intramedullary Nailing System

China's ZheJiang Decans Medical Devices Co., Ltd. obtained 510(k) clearance for its HERA Interlocking Intramedullary Nailing System for long bone fracture fixation.

Intelligence: This clearance provides the company with a foundational product to enter the US orthopedic trauma market, a necessary step to build relationships with surgeons and hospital networks.

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

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

Shenzhen Kaiyan Medical Equipment Co., Ltd. of China received 510(k) clearance for its LED Neck Beauty Mask, designed for aesthetic applications on the neck.

Intelligence: Targeting a specific anatomical area like the neck with an LED therapy device suggests a niche market strategy to differentiate from the more common full-face masks in the US aesthetics space.

🇰🇷 Medpark Co., Ltd. South Korea

BOSS

South Korea's Medpark Co., Ltd. secured 510(k) clearance for its BOSS, a bone cement injection system for use in orthopedic procedures.

Intelligence: This clearance for a delivery system could complement a broader orthopedic portfolio or serve as a standalone product for the company to enter the US surgical market.

🇰🇷 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. received 510(k) clearance for the DRE Duo, a mobile X-ray system.

Intelligence: This clearance for a complete mobile imaging system, rather than just a component, may signal a strategic move by Jpi Healthcare to capture more value by selling integrated systems directly into the US market.

🇰🇷 Crescom Co., Ltd. South Korea

> MediAI-OA

Crescom Co., Ltd. of South Korea secured 510(k) clearance for MediAI-OA, an AI-based software that assists in diagnosing osteoarthritis severity from knee X-ray images.

Intelligence: This clearance highlights a growing trend of Korean medtech firms developing AI-powered clinical decision support software, positioning them to compete in the high-growth US market for imaging analytics.

🇨🇳 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. obtained 510(k) clearance for its single and double lumen oocyte (egg) retrieval needles used in IVF procedures.

Intelligence: By providing essential disposable devices for IVF, the company is positioned to supply the growing number of fertility clinics in the US with critical consumables.

🇨🇳 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 competitors in the US durable medical equipment space, specifically targeting the personal mobility segment.

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

> Fule Interbody Fusion Cage System

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

Intelligence: Following its recent clearance for a trauma nail, this spine clearance demonstrates the company is actively building a diversified 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. from China obtained 510(k) clearance for a wide range of bone conduction hearing aid models.

> **Intelligence:** This clearance for numerous models at once may position Zdeer to compete in the newly established over-the-counter (OTC) hearing aid category in the US, which favors accessible, consumer-friendly technology.

🇨🇳 SteriLance Medical (Suzhou), Inc. China

> Disposable Blood Lancet (Soft)

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

> **Intelligence:** This clearance allows the company to supply a high-volume, disposable commodity product to the vast US market for diabetes monitoring and other point-of-care testing.

🇯🇵 Whill, Inc. Japan

> WHILL (WHILL Model C2)

Japan's Whill, Inc. secured 510(k) clearance for its WHILL Model C2, a personal electric mobility device.

> **Intelligence:** Known for its design-forward approach, this clearance for another of Whill's models reinforces its strategy of targeting the US personal mobility market with products that emphasize user experience and aesthetics over traditional medical designs.

🇨🇳 Sanhe LEFIS Electronics Co., Ltd. China

> Intense Pulsed Light Therapy Device

Sanhe LEFIS Electronics Co., Ltd. from China obtained 510(k) clearance for an Intense Pulsed Light (IPL) therapy device for hair removal.

> **Intelligence:** This clearance positions the company to compete in the US professional aesthetics market, supplying clinics and medspas with capital equipment for common cosmetic procedures.

🇰🇷 Lg Electronics.Inc South Korea

> Medical Monitor (40HT513D)

South Korea's LG Electronics Inc. received 510(k) clearance for its 40-inch medical monitor, designed for displaying medical images.

> **Intelligence:** This clearance expands LG's portfolio of specialized medical displays, leveraging its global leadership in screen technology to target high-resolution applications in US hospitals and imaging centers.

🇨🇳 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 secured 510(k) clearance for a wide range of electric breast pump models.

> **Intelligence:** The sheer number of models cleared at once suggests a strategy to serve as a versatile original equipment manufacturer (OEM) or to launch a broad product line targeting multiple segments of the US consumer market.

🇰🇷 Dyne Medical Group, Inc. South Korea

> DYNE PORT

Dyne Medical Group, Inc. of South Korea obtained 510(k) clearance for the DYNE PORT, an implantable vascular access port for delivering fluids and medications.

> **Intelligence:** This clearance for an implantable port allows the company to enter the US market for oncology and long-term infusion therapies, a segment that requires strong relationships with interventional radiologists and surgeons.

🇹🇼 Avita Corporation Taiwan

> AViTA Breast Pump

Taiwan's Avita Corporation received 510(k) clearance for its AViTA Electric Breast Pump.

> **Intelligence:** This clearance enables Avita to enter the competitive US market for mother and baby care products, a space with established brands and significant direct-to-consumer marketing.

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

> Fluoride Varnish (Type A,Type C)

China's Nagy Oral Technology Qinhuangdao Co., Ltd. secured 510(k) clearance for its fluoride varnish, a dental product used to prevent tooth decay.

> **Intelligence:** By gaining clearance for a preventative dental consumable, the company can target a high-volume, recurring-use product category within US dental practices.

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

> Dental X-ray System

Changzhou Boen Zhongding Medical Technology Co., Ltd. from China obtained 510(k) clearance for its dental X-ray system.

> **Intelligence:** This clearance for a core piece of dental imaging equipment positions the company to compete for sales to dental clinics in the US, likely focusing on the value-oriented segment.

🇰🇷 Hass Corp. South Korea

> Rosetta SM, Rosetta SP

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

> **Intelligence:** This clearance for CAD/CAM blocks strengthens Hass Corp.'s position in the US digital dentistry ecosystem, providing essential materials for dental labs and clinics that use milling machines.

🇯🇵 Hitachi High-Tech Corp. Japan

> PROBEAT-CR

Japan's Hitachi High-Tech Corp. secured 510(k) clearance for its PROBEAT-CR, a system for computed radiography in proton therapy treatment rooms.

> **Intelligence:** This clearance for an integrated imaging component is expected to reinforce Hitachi's established position as a leading provider of comprehensive proton therapy solutions to major US cancer centers.

🇨🇳 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 obtained 510(k) clearance for its bone conduction hearing aids.

Intelligence: The entry of another Chinese manufacturer into the bone conduction hearing aid space could increase competition and price pressure in the US over-the-counter (OTC) hearing device market.

🇨🇳 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 a system that provides both cold (cryo) and heat (thermo) therapy.

Intelligence: This clearance allows the company to target the US physical therapy, sports medicine, and rehabilitation markets with a device offering multiple treatment modalities.

🇹🇼 Alpha Intelligence Manifolds, Inc. Taiwan

DeepXray Spina

Alpha Intelligence Manifolds, Inc. from Taiwan secured 510(k) clearance for DeepXray Spina, an AI software that analyzes lumbar spine X-rays.

Intelligence: This clearance positions the Taiwanese AI company to offer a clinical decision support tool to US radiologists and orthopedic specialists, competing in the growing field of AI-driven medical image analysis.

🇹🇼 Tech-Image CO., LTD. Taiwan

“Tech-Image” Video Endoscope System

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

BOBBY Balloon Guide Catheter

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

Intelligence: The introduction of a new balloon guide catheter broadens MicroVention's comprehensive portfolio for stroke intervention, potentially strengthening its ability to win system-wide contracts with US hospitals.

🇨🇳 Shenzhen TPH Technology Co., Ltd. China

Mother's Nature W1 Warming Wearable Breast Pump

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

Intelligence: By incorporating a specific comfort feature like warming, the company may be attempting to differentiate its product in the increasingly crowded US market for wearable breast pumps.

🇰🇷 Sejong Medical Co., Ltd. South Korea

LAP-iX2N

South Korea's Sejong Medical Co., Ltd. obtained 510(k) clearance for the LAP-iX2N, a disposable laparoscopic instrument.

Intelligence: This clearance for a disposable surgical tool allows Sejong Medical to target the high-volume consumables segment of the US minimally invasive surgery market.

🇹🇼 Chanpin Medtak Co., Ltd. Taiwan

ChanPin Pedicle Screw Spinal System

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

Intelligence: This clearance marks an important step for the Taiwanese company to establish a foothold in the competitive and technically demanding US spinal implant market.

🇰🇷 Weero Co., Ltd. South Korea

Apollo Quattro (APQ-10M)

Weero Co., Ltd. from South Korea secured 510(k) clearance for its Apollo Quattro, a device that combines suction, radiofrequency, and laser functions for aesthetic treatments.

Intelligence: Offering a multi-modality platform could be a strategy to appeal to US aesthetic clinics looking to maximize the number of treatments they can offer with a single piece of capital equipment.

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

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

China's Jiangsu Intco Medical Products Co., Ltd., a major manufacturer of medical disposables, obtained 510(k) clearance for its Virgo Mobility Scooter.

Intelligence: This move into durable medical equipment like mobility scooters represents a product diversification strategy for Intco, leveraging its manufacturing scale to enter a new product category in the US.

🇨🇳 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. received 510(k) clearance for a range of disposable and reusable temperature probes.

Intelligence: By securing clearance for probes compatible with various patient monitoring systems, Unimed is positioned to compete as a third-party supplier of consumables to US hospitals.

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

> Vial Adapter

Hangzhou Qiantang Longyue Biotechnology Co., Ltd. from China secured 510(k) clearance for a vial adapter used for transferring drugs.

Intelligence: This clearance allows the company to supply a key component for drug reconstitution and administration systems, targeting US pharmacies and clinical settings where safe drug handling is critical.

🇨🇳 Zhejiang Innuovo Rehabilitation Devices Co.,Ltd China

> Power Wheelchair (N5515A, N5516, N5517A, N5519)

Zhejiang Innuovo Rehabilitation Devices Co., Ltd. of China obtained another 510(k) clearance for a different series of its power wheelchairs.

Intelligence: Receiving multiple clearances for different wheelchair models in a short time frame suggests the company is building a broad portfolio to address various user needs and price points in the US mobility market.

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

LumiGlam Laser System (SHE-LSP601-3)

China's Beijing Sano Laser S&T Development Co., Ltd. received 510(k) clearance for its LumiGlam Laser System, a multi-wavelength laser for hair removal and other aesthetic applications.

Intelligence: This clearance for a multi-functional laser platform enables the company to enter the US professional aesthetics market, competing with established capital equipment providers.

🇰🇷 Uzinmedicare Co., Ltd. South Korea

Spectra Platinum Mini

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

Intelligence: As the manufacturer for the well-known Spectra brand, this clearance for a new portable model is expected to strengthen its competitive position in the US consumer market for breast pumps.

🇨🇳 Yofo Medical Technology Co., Ltd. China

Dental Cone Beam Computed Tomography System

Yofo Medical Technology Co., Ltd. from China obtained 510(k) clearance for its Dental Cone Beam Computed Tomography (CBCT) System.

Intelligence: This clearance for an advanced 3D imaging system signals the company's ambition to move beyond basic dental equipment and compete in the higher-value diagnostics segment in the US.

🇨🇳 Keya Medical Technology Co., Ltd. China

DEEPVESSEL Plaque

China's Keya Medical Technology Co., Ltd. received 510(k) clearance for DEEPVESSEL Plaque, an AI software for analyzing plaque in coronary computed tomography angiography (CCTA) images.

Intelligence: The clearance of this specialized cardiovascular AI tool positions Keya Medical to compete in the sophisticated US market for advanced imaging software, potentially partnering with hospitals and imaging labs to enhance cardiac diagnostics.

💊 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-ADAMTS5 monoclonal antibody; first-in-class; subcutaneous injection.

WHY IT MATTERS

As a new molecular entity, this approval positions Viridian as a potential challenger to Amgen's blockbuster Tepezza in the thyroid eye disease market. Its subcutaneous administration offers a significant convenience advantage over the incumbent's intravenous infusion, which could drive market adoption.

FOSAPREPITANT NAVITRUX **New Formulation** AVYXA HOLDINGS

WHAT IT IS

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

WHY IT MATTERS

This new formulation of the established antiemetic fosaprepitant enters a competitive, largely genericized market. Its commercial success will likely depend on differentiating through improved convenience or securing favorable formulary placement with competitive pricing.

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 for a subcutaneous maintenance option in ulcerative colitis could enhance patient convenience, potentially strengthening Skyrizi's competitive profile against both existing therapies and anticipated biosimilars in the IBD space.

VIMSELTINIB ROMVIMZA New Formulation DECIPHERA PHARMS

WHAT IT IS

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

WHY IT MATTERS

This approval positions Romvimza as a direct competitor to the only other approved therapy, Turalio, and its potentially more favorable safety profile could allow it to capture significant market share in TGCT. For new owner ONO Pharmaceutical, this marks a successful entry into the U.S. rare disease market.

INCOBOTULINUMTOXINA XEOMIN New Formulation MERZ PHARMS

WHAT IT IS

IncobotulinumtoxinA is a botulinum neurotoxin type A, administered via intramuscular injection.

Adults with chronic sialorrhea.

WHY IT MATTERS

The approval for treating platysma bands expands Xeomin's aesthetic label, which may help Merz better compete against market leaders like Botox and Dysport in the highly lucrative and growing neurotoxin aesthetics market.

OLEZARSEN SODIUM TRYNGOLZA New Formulation Priority Review

IONIS PHARMS INC

WHAT IT IS

Olezarsen sodium is an apoC-III antisense oligonucleotide, administered via subcutaneous injection, with FDA Priority Review.

WHY IT MATTERS

As a second-generation antisense therapy with a potentially improved safety profile over the first-generation treatment, this approval in a rare disease could solidify Ionis's leadership in RNA-targeted therapeutics and may bolster confidence in their broader cardiometabolic pipeline.

PALBOCICLIB IBRANCE New Formulation PFIZER

WHAT IT IS

Palbociclib is an oral CDK4/6 inhibitor.

Men and pre/perimenopausal women with HR+, HER2- advanced or metastatic breast cancer.

WHY IT MATTERS

This label expansion to include male breast cancer patients is an incremental update that, while clinically important for this small population, is unlikely to alter the challenging competitive dynamics Ibrance faces from rival CDK4/6 inhibitors.

PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH KEYTRUDA QLEX

New Formulation

MERCK SHARP DOHME

WHAT IT IS

Pembrolizumab and berahyaluonidase alfa-pmph is a PD-1 inhibitor coformulation for subcutaneous injection.

WHY IT MATTERS

The approval of a subcutaneous formulation of Keytruda is a critical lifecycle management strategy for Merck, as it is expected to help protect the multi-billion dollar franchise from intravenous biosimilar competition anticipated after 2028.

PALBOCICLIB IBRANCE New Formulation

PFIZER

WHAT IT IS

Palbociclib is an oral CDK4/6 inhibitor.

Men and pre/perimenopausal women with HR+, HER2- advanced or metastatic breast cancer.

WHY IT MATTERS

Minor label updates for Ibrance represent routine lifecycle management but do not address the core competitive pressure from rivals that have demonstrated overall survival advantages in key patient populations.

PEMBROLIZUMAB KEYTRUDA New Formulation

MERCK SHARP DOHME

WHAT IT IS

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

Adults with unresectable or metastatic esophageal squamous cell carcinoma.

WHY IT MATTERS

This approval in a new first-line cancer setting further expands Keytruda's market, reinforcing its position as a foundational immuno-oncology agent as Merck continues to build its dominance ahead of future patent expirations.

SACITUZUMAB GOVITECAN TRODELVY New Formulation

IMMUNOMEDICS INC

WHAT IT IS

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

Adults with unresectable locally advanced or metastatic HR+/HER2- breast cancer.

WHY IT MATTERS

Securing approval in the large HR+/HER2- metastatic breast cancer market significantly expands Trodelvy's commercial potential beyond its initial niche indications, positioning it as a key antibody-drug conjugate in breast cancer treatment.

SACITUZUMAB GOVITECAN TRODELVY **New Formulation** IMMUNOMEDICS INC

WHAT IT IS

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

Adults with unresectable locally advanced or metastatic HR+/HER2- breast cancer.

WHY IT MATTERS

Each additional approval for Trodelvy helps Gilead build a stronger clinical data package and market presence ahead of the potential entry of competing TROP-2 directed ADCs, such as datopotamab deruxtecan.

🩺 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 decisions.

saypha® ChiQ™

Croma-Pharma GmbH

> Dermal filler for restoring facial volume, smoothing wrinkles, or enhancing facial contours.

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 for improving skin smoothness and hydration, often in the face.

510(k) Clearances (most recent 10)

Device	Applicant	Date
Dynamis Robotic Surgical System Robotic surgical system for assisting surgeons in performing various surgical 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.	True Indicating, LLC	2026-06-18
SteriBest® Sterilization Tray System Sterilization tray system for holding and organizing surgical instruments during sterilization and storage.	Mastel Surgical	2026-06-18

SmartSpectra Vital Signs Monitor 1.0 Vital signs monitor for measuring and displaying physiological parameters like heart rate and oxygen saturation.	Presage Security, Inc. d/b/a Presage Technologies, Inc.	2026-06-18
ARTHUR Medical device — Robotic system for assisting in surgical procedures.	ROPCA ApS	2026-06-18
Pelvic Muscle Trainer (KM510, KM516B) Pelvic muscle trainer for strengthening pelvic floor muscles to treat incontinence or improve pelvic health.	Shenzhen Konmed Technology Co., Ltd.	2026-06-18
MegaGen Zygoma Dental Implant System Dental implant system for providing a stable foundation for prosthetic teeth in patients with bone 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 system for limb lengthening and reconstruction, including ankle salvage procedures.	NuVasive Specialized Orthopedics	2026-06-18
Implantmed Plus II & Piezomed Plus II Module Dental surgical system for performing implant procedures and piezoelectric bone surgery.	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 caused the drugs to be 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) held by Endo Operations Limited, et al. It affects pharmaceutical manufacturers of these specific drug products.

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

This Notice is a correction to a previous request for information concerning the Expedited Investigational New Drug (IND) Pilot Program. It affects pharmaceutical companies developing new drugs seeking expedited review.

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 determines that VASOPRESSIN IN SODIUM CHLORIDE injection was not withdrawn from sale for safety or effectiveness reasons. This affects generic drug manufacturers seeking to market a generic version.

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 a medical device. It affects manufacturers of anesthesiology devices and related monitoring technology.

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 medical device. It affects manufacturers of general and plastic surgery devices for dermatological conditions.

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 a medical device. It affects manufacturers of orthopedic devices, specifically 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 a Biologics License Application (BLA) for Deramiocel. It affects biologics manufacturers, especially those in cellular and gene therapies.

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

This Notice determines the regulatory review period for VYALEV, impacting its patent extension. It affects pharmaceutical companies holding patents for this drug.

FDA Weekly Intelligence

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

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