

New FDA 510(k) Clearances — Weekly Digest (Sample Issue)

Decision dates **Sep 12, 2026 – Oct 11, 2026** · 278 decisions · Source: openFDA (last updated per API meta) · Sample by Sunhour Capital

By specialty: Radiology 41 · Orthopedic 37 · Cardiovascular 36 · General, Plastic Surgery 30 · Dental 22 · Gastroenterology, Urology 20 · Physical Medicine 19 · Microbiology 13 · Neurology 12 · Anesthesiology 9 · Clinical Chemistry 8 · Obstetrics/Gynecology 8 · General Hospital 7 · Unknown 6 · Ear, Nose, Throat 4 · Hematology 2 · Ophthalmic 2 · Immunology 1 · Pathology 1

Most active applicants: Karl Storz SE & CO. KG (4) · Zhenjiang Assure Medical Equipment Co., Ltd. (4) · Roche Diagnostics (3) · Anhui JBH Medical Apparatus Co., Ltd. (3) · Fujifilm Corporation (3) · CMT Health PTE., Ltd. (2) · Sorin Group Italia S.R.L. (2) · Elucid Bioimaging, Inc. (2) · DiaDent Group International (2) · Spident Co., Ltd. (2)

By country: US 126 · CN 49 · KR 24 · DE 17 · JP 7 · IT 6 · IL 5 · BE 5

Radiology (41)

Who should care: Imaging OEMs, AI-imaging startups, radiology groups, PACS vendors

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-14	K261517	qCT Lung (v1.0)	QDQ / 2	Qure.AI Technologies Pvt. , Ltd.	Mumbai, IN	Smina T P
2026-09-15	K261861	SPINEsim v1.0	LLZ / 2	Mdsim S.A.	Esch-Sur-Alzette, LU	Dany Assaker
2026-09-15	K261677	Artificial Intelligence Renal Assessment (AIRA) Version 1	QIH / 2	Aramis Global AI Consultancies, LLC	Dubai, AE	Anil Prahladan
2026-09-15	K254214	OOOPDS	LLZ / 2	Taiwan Main Orthopaedic Biotechnology Co., Ltd.	Taichung, TW	Jacky Fan
2026-09-16	K261865	AerFrame□ Alignment Laser Box (LBV2)	IYE / 2	Stabilix, LLC	Dallas, TX, US	Richard Westhoven
2026-09-16	K261283	APERTO Lucent MRI System	LNH / 2	Fujifilm Corporation	Minato-Ku, JP	Chaitrali Kulkarni
2026-09-16	K261623	EchoPAC Software Only / EchoPAC Plug-in (v211)	QIH / 2	GE Medical Systems Ultrasound and Primary Care Diagnostics	Waukesha, WI, US	Charlotte Joergensen
2026-09-16	K261758	Embrace Vision Neonatal MRI System	LNH / 2	Aspect Imaging, Ltd.	Shoham, IL	Yaron Eshel
2026-09-16	K260906	a2z-Abdo-Triage	QAS / 2	A2z Radiology Ai, Inc.	Boston, MA, US	Samir Rajpurkar

2026-09-18	K261229	SCENARIO View Phase 6.0	JAK / 2	Fujifilm Corporation	Minato-Ku, JP	Chaitrali Kulkarni
2026-09-18	K261855	Elucid PlaqueIQ	LLZ / 2	Elucid Bioimaging, Inc.	Boston, MA, US	Hiral Vora
2026-09-21	K261368	Rapid Platform (R6.7)	QIH / 2	Ischemaview, Inc.	Golden, CO, US	James Rosa
2026-09-22	K261125	BodyTom 64 (NL4100); OmniTom Elite (NL5000)	JAK / 2	Samsung HME America, Inc., dba NeuroLogica Corp.	Danvers, MA, US	Ninad Gujar
2026-09-22	K262390	BoneXpert	QIH / 2	Visiana	Horsholm, DK	Hans Henrik Thodberg
2026-09-22	K262442	HipStudio Analysis	LLZ / 2	Replasia BV	Leuven, BE	Tim Van Cleynenbreugel
2026-09-23	K260597	VIRTUE QA	LHN / 2	ProNova Solutions	Maryville, TN, US	Amy Bellendir
2026-09-23	K261874	Syneris PACS v.1.0.1.0	LLZ / 2	Syneris	Concord, CA	Lily Timonina
2026-09-24	K260313	MD-6000S Bladder Scanner	IYO / 2	MEDA Co., Ltd.	Tianjin, CN	Linda Zhang
2026-09-24	K260114	Align® Cover and Pad Guidance Tool	ITX / 2	CIVCO Medical Instruments Co., Inc.	Coralville, IA, US	James Leong
2026-09-25	K263182	EVO X30 Diagnostic Ultrasound System; EVO X20 Diagnostic Ultrasound System; EVO X10 Diagnostic Ultrasound System; EVO XP30 Diagnostic Ultrasound System; EVO XP20 Diagnostic Ultrasound System; EVO XP10 Diagnostic Ultrasound System; EVO XC30 Diagnostic Ultrasound System; EVO XC20 Diagnostic	IYN / 2	Samsung Medison Co., Ltd.	Hongcheon-Gun, KR	Dayoung Choi

		Ultrasound System; EVO XC10 Diagnostic Ultrasound System				
2026-09-25	K262548	EPIQ Inspira Series Diagnostic Ultrasound System; Affiniti Series Diagnostic Ultrasound System	IYN / 2	Philips Ultrasound, LLC	Bothell, WA, US	Swetha Paritala
2026-09-25	K260055	syngo.CT Brain Quantification	QIH / 2	Siemens Medical Solutions USA, Inc.	Knoxville, TN, US	Kenny M Bello
2026-09-29	K261225	CAS-One IR	JAK / 2	Cascination AG	Bern, CH	Salleles Gordana
2026-09-29	K263048	Syngo Carbon Space (VA4)	LLZ / 2	Siemens Healthineers AG	Forchheim, DE	Vijay Ramadas
2026-09-30	K263033	Dental Computed Tomography X-ray System (Rubik XSmart, Rubik X1, Rubik X3) (Matrix 7000, Matrix 7800)	OAS / 2	Fussen Technology Co., Ltd.	Shenzhen, CN	Guiqin Zheng
2026-10-01	K261612	SwiftSight-BodyComposition	LNH / 2	Airs Medical, Inc.	Seoul, KR	Markus Cho
2026-10-02	K262985	Medical Monitor (32MD08WC)	PGY / 2	Lg Electronics.Inc	Gumi-Si, KR	Wonhi Lee
2026-10-02	K261933	Voluson Expert 18; Voluson Expert 20; Voluson Expert 22	IYN / 2	GE Medical Systems Ultrasound and Primary care Diagnostics, LLC	Waukesha, WI, US	Bryan Behn
2026-10-02	K261042	Lung Guidance	QJU / 2	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC	Waukesha, WI, US	Zahra Ghanian
2026-10-02	K262412	Coronis Fusion 4MP (MDCC-4630); Coronis	PGY / 2	Barco NV	Kortrijk, BE	Lieven De Wandel

		Fusion 6MP (MDCC-6630)				
2026-10-02	K261943	REMEX-T(K)100C	IZL / 2	Remedi, Inc.	Seoul, KR	Seong-Geun Park
2026-10-05	K262813	InkSpace Imaging Small Body Array (SBA12PH15x)	MOS / 2	InkSpace Imaging, Inc.	Pleasanton, CA, US	Peter Fischer
2026-10-05	K260523	QGuideCT (1.0)	QIH / 2	Medis Medical Imaging Systems BV	Leiden, NL	Bob Goedhart
2026-10-05	K261655	RT Elements (4.6)	MUJ / 2	Brainlab SE	Munich, DE	Sadwini Suresh
2026-10-07	K262134	NeuroDR	QIH / 2	Deep Reasoning Ai, Inc.	Sarasota, FL, US	Jeanne Usonis
2026-10-07	K261733	Ligence Heart	QIH / 2	UAB Ligence	Kaunas, LT	Alvaro Perez-Moreno
2026-10-07	K260092	Vista AI Scan	LNH / 2	Vista AI, Inc.	Palo Alto, CA, US	James Rogers
2026-10-08	K261617	Diagnostic Ultrasound System (Resona I10W);Diagnostic Ultrasound System (Resona I10 Exp);Diagnostic Ultrasound System (Resona I10);Diagnostic Ultrasound System (Resona I10S);Diagnostic Ultrasound System (Resona XI);Diagnostic Ultrasound System (Resona I10 CV);Diagnostic Ultrasound System (Nuewa I10W);Diagnostic Ultrasound System (Nuewa I10 Exp);Diagnostic Ultrasound System (Nuewa	IYN / 2	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen, CN	Jing Tang

		I10);Diagnostic Ultrasound System (Nuewa I10S);Diagnostic Ultrasound System (Nuewa XI);Diagnostic Ultrasoun				
2026- 10-08	K263150	V10 Diagnostic Ultrasound System; cV10 Diagnostic Ultrasound System; H10 Diagnostic Ultrasound System; XV10 Diagnostic Ultrasound System; XH10 Diagnostic Ultrasound System; V10 ONE Diagnostic Ultrasound System; cV10 ONE Diagnostic Ultrasound System; H10 ONE Diagnostic Ultrasound System; XV10 ONE Diagnostic Ultrasound System; XH10 ONE Diagnostic Ultrasound System; HERA Z10 Diagnostic Ultrasound System	IYN / 2	Samsung Medison Co., Ltd.	Hongcheon- Gun, KR	Yoojung Choi
2026- 10-09	K262301	Rapid ICH (v4.0)	QAS / 2	Ischemaview, Inc.	Golden, CO, US	James Rosa
2026- 10-09	K262902	ECHELON Synergy	LNH / 2	Fujifilm Corporation	Minato-Ku, JP	Chaitrali Kulkarni

Orthopedic (37)

Who should care: Implant distributors, ortho contract manufacturers, ASC purchasing

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
------	----	--------	------------	-----------	----------	-----------------------

2026-09-14	K262193	RIVA® Posterior Fixation System with NanoACTIV Surface Technology; RIVA® Anchor Sacroiliac Fixation System with NanoACTIV Surface Technology	NKB / 2	Xenix Medical	Orlando, FL, US	Tyler Holschlag
2026-09-15	K262057	GMK Extension	JWH / 2	Medacta International SA	Castel San Pietro, CH	Stefano Baj
2026-09-15	K262963	TMC Implant Fixation System	HRS / 2	Treace Medical Concepts, Inc.	Ponte Vedra, FL, US	Melissa Coloroso
2026-09-17	K254260	The VEGA Cervical Screw System	NKG / 2	GS Medical Co., Ltd.	Cheongju, KR	Sun Ju Choi
2026-09-17	K261869	Integrity Retractable Implant Inserter (6000127)	MBI / 2	Anika Therapeutics, Inc.	Beford, MA, US	Calen Souther
2026-09-17	K260173	M-Vizion Femoral Revision System Extension	LZO / 2	Medacta International S.A.	Castel San Pietro, CH	Stefano Baj
2026-09-17	K262091	FRAXION Spinal Fixation System	NKB / 2	Ortler Global Tibbi Gerecler Anonim Sirketi	Ankara, TR	TAHA CIBIR
2026-09-17	K261275	Unity Total Knee System, Unity Knee Cementless CR Femur	MBH / 2	Corin, Ltd.	Cirencester, GB	Marine De Paoli
2026-09-18	K262098	EnHAnce PEEK Bunion System	HRS / 2	Nvision Biomedical Technologies	San Antonio, TX, US	Marisa Zink
2026-09-21	K254280	F.A.S.T Screw	HWC / 2	Steps Ortho	Bron, FR	Morgane Grenier
2026-09-23	K261892	ProRib Fixation System	HRS / 2	Costa Surgical, Inc.	Chandler, AZ, US	Nick Slater
2026-09-23	K261453	G7® Acetabular System	LPH / 2	Zimmer Biomet	Warsaw, IN, US	Nicole Meredith
2026-09-23	K263049	SABER-C System	OVE / 2	Elevation Spine	Monteray, CA, US	John Kirwan
2026-09-23	K262067	iFuse Granite Onyx□ Implant System	NKB / 2	SI-BONE, Inc.	Santa Clara, CA, US	Jayasri Prabakaran
2026-09-23	K260995	DynaNail Helix® Fixation System	HWC / 2	MedShape, Inc.	Atlanta, GA, US	Lauren Livsey

2026-09-24	K262149	corra® cervical plating system	KWQ / 2	Carlsmed, Inc.	Carlsbad, CA, US	Jesse Albright
2026-09-24	K262955	OsseoFit Stemless Shoulder System	PKC / 2	Zimmer, Inc.	Warsaw, IN, US	Alexandria Irwin
2026-09-24	K261345	Pediatric Nailing Platform Femur	HSB / 2	OrthoPediatrics Corp.	Warsaw, IN, US	Jessica Powers
2026-09-25	K262975	Arthrex Beaming System	HWC / 2	Arthrex, Inc.	Naples, FL, US	Konrad Wolfmeyer
2026-09-27	K252139	Kentrospine Viktr-MIS® Pedicle screw system	NKB / 2	Rivarp Medical Pvt., Ltd.	Bangalore, IN	Sushma N.R
2026-09-28	K262649	Alians Forearm	HRS / 2	Newclip Technics	Haute-Goulaine, FR	Gaëlle Gourbière
2026-09-29	K262726	NeckTune□ SA Cervical Cage	OVE / 2	Medyssey Co., Ltd.	Jecheon-Si, KR	Yujin Go
2026-09-29	K262721	Spinalogic Bone Growth Stimulator	LOF / 2	Djo, LLC	Carlsbad, CA, US	Mitchell Dhority
2026-09-30	K262712	Duet□ Spinal Fixation System	NKB / 2	Duet Spine Holdings, LLC	Winona Lake, IN, US	Jill Serbousek
2026-09-30	K263172	SAS MIS Pelvic Incidence Rods	NKB / 2	Spinal Alignment Solutions, Inc.	Wilmington, NC, US	Bassel Diebo
2026-10-01	K262473	NEXUS® Hip Stem	LZO / 2	Microport Orthopedics, Inc.	Arlington, TN, US	Hunter Williams
2026-10-01	K263062	NOVIX Pedicle Screw System	NKB / 2	Tdm Co., Ltd.	Gwangju, KR	Jungwook Choi
2026-10-02	K261607	Minuteman G6 MIS Fusion Plate; Minuteman G5 MIS Fusion Plate; Minuteman G1 (Posterior Fusion Plate /HA Posterior Fusion Plate); HA Minuteman G3-R MIS Fusion Plate; Minuteman G3/HA Minuteman G3; Patriot SI Implant System; Liberty SI Lateral Implant System	PEK / 2	Spinal Simplicity, LLC	Overland Park, KS, US	Adam Rogers
2026-10-02	K261217	AnyPlus II Spinal Fixation System	NKB / 2	GS Medical Co., Ltd.	Cheongju-Si, KR	Kim Seon Yeon

2026-10-02	K263086	AltiVate Reverse® Glenosphere with RAVN□ Technology	PHX / 2	Encore Medical L.P.	Austin, TX, US	Patricia Kontoudis
2026-10-02	K263113	ZSAlign Cervical Interbody System	OVE / 2	ZSFab, Inc.	Waltham, MA, US	David Ma
2026-10-02	K263116	OsteoCentric Technologies Cannulated and Solid Fasteners with Nuts	HWC / 2	OsteoCentric Technologies	Logan, UT, US	Stacey Prisbrey
2026-10-02	K261611	TDM Large Bone Plate and Screw System	HRS / 2	Tdm Co., Ltd.	Gwangju, KR	Jungwook Choi
2026-10-02	K263083	Response Ortho Smart Fixator - Hexapod System	KTT / 2	Response Ortho Solutions, LLC	Boynton Beach, FL, US	ISIN Sehmuz
2026-10-07	K263159	prodisc® C; prodisc® C SK; prodisc® C Nova; prodisc® C Vivo Instruments	QLQ / 2	Centinel Spine, LLC	West Chester, PA, US	Hayley Parry
2026-10-07	K261120	APEX 3D S Diamond Tibia	HSN / 2	Paragon 28, Inc.	Englewood, CO, US	Jacqueline Sloan
2026-10-09	K260156	TruVision Single-Use 1.9mm Arthroscopy System	HRX / 2	Nexus CMF, LLC	Salt Lake City, UT, US	Wittwer Tiffini

Cardiovascular (36)

Who should care: Cath-lab suppliers, cardiology practices, component/catheter contract manufacturers

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-12	K261287	Digistat Care	MSX / 2	Ascom Ums Srl Unipersonale	Scandicci (Fi), IT	Tomaso Muzzu
2026-09-14	K261438	HORIZON 8AF (Integrated OXY MODULE 8AF and Horizon CVR) (US5305)	DTZ / 2	Eurosets S.R.L	Medolla, IT	Katia Vescovini
2026-09-14	K261089	Radical 064 Reperfusion Catheter; Radical 076 Reperfusion Catheter; Radical	NRY / 2	Maduro Medical, Inc.	Los Gatos, CA, US	Janice Kemp

		Aspiration Tubing Kit				
2026-09-16	K254181	Aristotle 65 Macrowire	MOF / 2	Scientia Vascular	West Valley City, UT, US	Bailey Johannsen
2026-09-16	K254212	NC PTA Balloon Dilatation Catheter	LIT / 2	Kossel Medtech (Suzhou) Co., Ltd.	Suzhou New District, CN	Haifeng Xie
2026-09-16	K261778	JADE SCORE PTA Scoring Balloon Dilatation Catheter	PNO / 2	OrbusNeich Medical (Shenzhen) Co., Ltd.	Shenzhen, CN	Dora Zhang
2026-09-16	K260220	Route 92 Medical Full Length 046 Access System	QJP / 2	Route 92 Medical, Inc.	San Mateo, CA, US	Kirsten Valley
2026-09-17	K261729	EnSite [®] X EP System	DQK / 2	Abbott Medical	St. Paul, MN, US	Hailey Christian
2026-09-18	K262817	CrossFAST Integrated Microcatheter Advanced Delivery System	DQY / 2	Vantis Vascular, Inc.	San Jose, CA, US	Mai-Ly Wilcox
2026-09-18	K253419	Trierer Duo Catheter	QEW / 2	Inari Medical, Inc.	Irvine, CA, US	Kaitlyn Weinkauff
2026-09-18	K260008	Deterioration Index Version 2	QNL / 2	Epic Systems Corporation	Verona, WI, US	Brian Jacobson
2026-09-18	K253146	Hyperdrive 35 Guidewire	DQX / 2	Rapid-Medical , Ltd.	Yokneam, IL	Gutman Ina
2026-09-21	K253509	TriSalus TriNav Advance Infusion System	KRA / 2	Trisalus Life Sciences	Westminster, CO, US	Michael Aymami
2026-09-21	K260416	ZYLOX Hippo PTA Balloon Dilatation Catheter	LIT / 2	Zylox Medtech Co., Ltd.	Hangzhou, CN	Wanying Xie
2026-09-22	K254240	Echo-2	QOK / 2	Neko Health AB	Danderyd, SE	Per Sundström
2026-09-25	K254058	DistaSense(TM) (v1)	DRT / 2	Life Detection Technologies	Sunnyvale, CA, US	Peter Rule
2026-09-25	K254255	S-Patch CardioAI	DPS / 2	Wellysis Corp.	Seoul, KR	Young Juhn
2026-09-25	K254297	Tempus ECG-MR	SBQ / 2	Tempus AI, Inc.	Chicago, IL, US	Bethany Barrett
2026-09-28	K262052	Tri Stage Venous Cannulae	DWF / 2	Sorin Group Italia S.R.L.	Mirandola, IT	Luigi Vecchi

2026-09-29	DEN260007	SmartRead(TM) Medical Device Identifier (4100)	SJJ / 2	BridgeSource Medical Corporation	Austin, TX, US	John Walmsley
2026-09-29	K260250	QCA 10 Electrocardiograph (QCARD-10); QCA 10W Electrocardiograph (QCARD-10W)	DPS / 2	QT Medical, Inc.	Diamond Bar, CA, US	Irving Yu
2026-09-29	K262015	Elucid FFR-IQ (B.1)	PJA / 2	Elucid Bioimaging, Inc.	Boston, MA, US	Windi Hary
2026-09-30	K261469	Nexxis 2;Nexxis OR 2;NMS 2;MNA-240;MNA-4x0 (Where □x□ may be any numeric character).	DXJ / 2	Barco N.V.	Kortrijk, BE	Eric Caus
2026-09-30	K254302	ECG Analysis Software (AiTiALVSD)	QYE / 2	Medical AI Co., Ltd.	Gangnam-Gu, Seoul, KR	Hyeri Choi
2026-10-01	K263016	Intra-Operative Positioning System (IOPS) and IOPS Visionary System	DQK / 2	Centerline Biomedical	Warrensville Heights, OH, US	Jill Godfrey
2026-10-01	K260470	Electronic Blood Pressure Monitor (BP-204C, BP-204A, BP-215, BP-203C, BP-205A, BP-201C, BP-217, BP-202C, BP-202 BP-205, BP-205B,BP-206)	DXN / 2	Shenzhen Brav Electronic Technologies Co., Ltd.	Shenzhen, CN	JinRan Bleu
2026-10-01	K263092	Dual Stage Venous Cannulae	DWF / 2	Sorin Group Italia S.R.L.	Mirandola, IT	Luigi Vecchi
2026-10-02	K253422	OAB Delivery Catheter	QJP / 2	Cognition Medical Corp.	Atlanta, GA, US	Alex Turjman
2026-10-02	K260490	Ninenovo Blood Oxygen Ring (BORMB-01-6,BORMB-01-7,BORMB-01-8,BORMB-01-9,BORMB-01-10,BORMB-01-11,BORMB-01-	DQA / 2	Shenzhen Ninenovo Technology Limited	Shenzhen, CN	Guoxing Wang

		12,BORMB-01-13,BORMB-01-14)				
2026-10-05	K260005	MyoVista wavECG (DG-200-B15-003)	DPS / 2	HeartSciences, Inc.	Southlake, TX, US	Isabella Schmitt
2026-10-06	K262798	LOBO Vascular Occlusion System	KRD / 2	Okami Medical, Inc.	Aliso Viejo, CA, US	Chelsea Gutierrez
2026-10-06	K262043	MEDRAD® MRXperion MR Injection System and MR Injection System Syringe Kit; MEDRAD® IS12 Module (IS12); MEDRAD® Imaging Bulk Package Transfer Spike	DXT / 2	Bayer Medical Care, Inc.	Indianola, PA, US	Troy Jack
2026-10-06	K261938	APRO 88 Catheter	QJP / 2	Alembic, LLC	Mountain View, CA, US	Lisa Yen
2026-10-07	K260075	eClinics	MSX / 2	Ceiba Healthcare US, Inc.	New York, NY, US	Afsin Alp
2026-10-09	K262068	Khelix Magnetic Sensor Electrophysiology Catheter (SS1-*-* MAG)	DRF / 2	CathRx, Ltd.	Rydalmere, AU	Henry Le
2026-10-09	K261649	Excelsior Reach Microcatheter	QJP / 2	Stryker Neurovascular	Fremont, CA, US	Katelynn Kirby

General, Plastic Surgery (30)

Who should care: Surgical distributors, aesthetic clinics, wound-care suppliers

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-13	K262526	Safety lancet (XL)	FMK / 2	Tianjin Huahong Technology Co., Ltd.	Tianjin, CN	Ningning Wang
2026-09-15	K261070	LigaSure□ RAS Maryland Jaw Vessel Sealer/Divider, Nano-coated	GEI / 2	Covidien, LLC	Lafayette, CO, US	Marissa Miller
2026-09-16	K262877	SOLTIVE□ Laser System (SOLTIVE□ Pro SuperPulsed	GEX / 2	Olympus Surgical	Westborough, MA, US	Dolan Mills

		Laser, SOLTIVE□ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)		Technologies America		
2026-09-16	K261467	GT Metabolic Magnet System (MAG-04, DS-01)GT Metabolic Magnet System (MAG-05, DS-01)	SAH / 2	Gt Metabolic Solutions, Inc.	St. Michael, MN, US	Lisa Griffin Vincent
2026-09-17	K254196	HARMONIC 1100 Shears (HAR1120); HARMONIC 1100 Shears (HAR1136)	GEI / 2	Ethicon Endo-Surgery, LLC	Guaynabo, PR, US	Hillary Lewis
2026-09-17	K261959	Neptune® SafeAir® 10ft Smoke Evacuation Pencil, Square Coated, 70mm Blade, Push Button Switch (0703-046-100);Neptune® SafeAir® 10ft Smoke Evacuation Pencil, Square Coated, Push Button Switch, Bulk Non-Sterile (0703-046-102);Neptune® SafeAir® 10ft Smoke Evacuation Pencil, Square Coated, 70mm Blade, Rocker Switch (0703-047-100);Neptune® SafeAir® 10ft Smoke Evacuation Pencil, Square Coated, Rocker Switch, Bulk Non-Sterile (0703-047-102)	GEI / 2	Stryker Instruments	Portage, MI, US	Jessica Brophy
2026-09-17	K261673	LED Therapy Device (QLXY-01)	GEX / 2	Beijing Nubway S&T Co., Ltd.	Beijing, CN	Xiting Fan
2026-09-17	K260677	Vessel Closure Device (VCD177213P)	FZP / 2	Vcd Medical S.R.L.	Brescia, IT	Francesco Piccagli
2026-09-17	K261817	Diode Laser Therapy System (PZ-BDT67-01, PZ-BDT67-02)	GEX / 2	Zhengzhou PZ Laser Slim	Zhengzhou, CN	Xinye Li

				Technology Co., Ltd.		
2026-09-17	K262073	Hygienic Protective Bite Cover (2207-010-50)	PEM / 2	Dürr Dental SE	Bietigheim-Bissingen, DE	Oliver Lange
2026-09-18	K262524	Sapphire Cooling IPL Hair Removal Device (Ice 2.0, Ice 2.1, Ice 2.2, Ice 2.0B, Ice 2.1B, Ice 2.2B)	OHT / 2	ONE BEAUTY Technology Co., Ltd.	Shenzhen, CN	Ninghua Pan
2026-09-18	K261047	Dental Diode Laser Device (Laser-Pen)	GEX / 2	Guilin Kevin Peter Technology Co., Ltd.	Guilin, CN	Libin Zhang
2026-09-18	K254160	VacHeal Negative Pressure Wound Therapy System	OKO / 2	VacHeal, LLC	Ardmore, PA, US	Tiffany Morrison
2026-09-18	K254238	MINT MONO Sutures	NEW / 2	Hans Biomed Corporation	Yuseong-Gu, KR	Mark Bae
2026-09-19	K252723	Dynamis Pro Family	GEX / 2	Fotona D.O.O.	Ljubljana, SI	Tina Bartolic
2026-09-19	K241973	SmartIPL_NI System	GEX / 2	Lumenis Be, Ltd.	Yokneam Ilit, IL	Shlomit Segman
2026-09-22	K243223	Multiple therapy aesthetic treatment device (BHS 202 UNIQUE)	PBX / 2	Bh Group Us, LLC	Davie, FL, US	Diego Bazzurro
2026-09-24	K254199	PicoreMax (PicoreMax)	GEX / 2	BLUECORE COMPANY Co., Ltd.	Yangsan, KR	Kwon Bu Gyeong
2026-09-25	K261977	Braun Aura 9 (6042)	OHT / 2	Cyden Limited	Swansea, GB	Matthew Silverberg
2026-09-25	K254291	easyEndo□ E-Lite Single Use Powered Endoscopic Staplers; easyEndo□ E-Lite Single Use Powered Endoscopic Staplers with Curved Tip; easyEndo□ E-Lite Single Use Cartridges	GDW / 2	Ezisurg Medical Co., Ltd.	Shanghai, CN	Hong Zhu
2026-09-28	K260474	Liora Monofilament Scaffold	FTL / 2	TELA Bio, Inc.	Malvern, PA, US	John Urtz

2026-09-28	K261543	Phasix ST Parastomal Hernia Mesh	OWT / 2	Davol, Inc., A Subsidiary of C.R. Bard, Inc.	Warwick, RI, US	Shannon Green
2026-09-29	K263073	Fast Absorbing PGLA	GAM / 2	Riverpoint Medical, LLC	Portland, OR, US	Rose Nakaweesi
2026-09-30	K261975	Braun Aura 7 (6041)	OHT / 2	CyDen Limited	Swansea, GB	Matthew Silverberg
2026-10-05	K262285	UV Phototherapy Device (KZX-308nm-BL65, KZX-308nm-BL55, KZX-308nm-BL50, KZX-308nm-BL45, KZX-308nm-BL35)	FTC / 2	Shijiazhuang Recovery Star Medical Device Co., Ltd.	Shijiazhuang, CN	Adrian Tse
2026-10-07	K262822	Nasal Aspirator (TLC-N02); Electric NoseFrida Pro (12300400); Electric NoseFrida (12100401)	BTA / 2	Zhongshan GL Electronics Co. , Ltd.	Zhongshan, CN	Cassie Gao
2026-10-07	K261692	Diode Laser Hair Removal Machine (QDTM-03)	GEX / 2	Beijing Nubway S&T Co., Ltd.	Beijing, CN	Xiting Fan
2026-10-08	K262346	CureLight Medical Diode Laser Systems (S3-BF45);CureLight Medical Diode Laser Systems (S2-B30);CureLight Medical Diode Laser Systems (S3-BF30);CureLight Medical Diode Laser Systems (S2-F15);CureLight Medical Diode Laser Systems (S2-H7.5)	GEX / 2	Wuhan Phomed Technology Co., Ltd.	Wuhan, CN	Xuhua Huang
2026-10-08	K260426	MeCare Alpha (MCA2019)	OMP / 2	IVT Medical, Ltd.	Ra'Anana, IL	Moris Topaz
2026-10-09	K262352	IPL Hair Removal Device (AHR01, R3C16-G Pro1, AHR02, AHR03, R4820, R6715, L3B02, JR20, R6312, R6202)	OHT / 2	Shenzhen Jianchao Intelligent Technology Co., Ltd.	Shenzhen, CN	Renne Qin

Dental (22)

Who should care: Dental distributors, dental labs, DSO procurement

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-14	K260795	Hand-held Dental X-ray System (HyperLight-M)	EHD / 2	Changzhou Sifary Medical Technology Co., Ltd.	Changzhou, CN	Qingfei Pan
2026-09-16	K254152	Dia-X Sil Light Body	ELW / 2	DiaDent Group International	Cheongju-Si, KR	Jin An
2026-09-16	K254142	Dia-X Sil Heavy Body	ELW / 2	DiaDent Group International	Cheongju-Si, KR	Jin An
2026-09-16	K261888	ClearClub Impression Material	SHI / 2	ClearClub	Inglewood, CA, US	Pablo Osorio
2026-09-17	K261392	TriActive Dental Implant System	DZE / 2	Paragon Implant Mfg., LLC	Calabasas, CA, US	Renee Bennett
2026-09-21	K260940	BellaTek Bars	NHA / 2	ZimVie US Corp, LLC	Palm Beach Gardens, FL, US	Ana Leitão
2026-09-21	K262982	Core-it Dual	EBF / 2	Spident Co., Ltd.	Incheon, KR	Seong Kiyong
2026-09-23	K262207	Cemented Plus Abutment	NHA / 2	Unidental Co., Ltd.	Gwangmyeong-Si, KR	Sungjoon Yang
2026-09-23	K262144	DIAMED Handpiece;DIAMED Airmotor;DIAMED Airmotor Handpiece	EFB / 1	SETAGAYA SEIKI Co., Ltd.	Yonezawa-City, JP	Shigehiro Sasaki
2026-09-24	K262252	MPa Max adhesive	KLE / 2	Den-Mat Holdings, LLC	Lompoc, CA, US	Brianna Alvarez
2026-09-25	K254210	REBOHIL (BGM-1, BGM-2, BGM-3, BGM-4, BGM-5)	NPM / 2	Hyundai Bioland Co., Ltd.	Cheongju-Si, KR	Seo Yeji
2026-09-25	K262983	EsTemp Implant	EMA / 2	Spident Co., Ltd.	Incheon, KR	Seong Kiyong
2026-09-25	K262196	Invisalign System	PNN / 2	Align Technology, Inc.	San Jose, CA, US	Sindhura Gaddamanugu
2026-09-30	K261663	EzSensor HD	MUH / 2	Qpix Solutions, Inc.	Morrisville, NC, US	Keedock Kim

2026-09-30	K261327	Elos Accurate Hybrid Base	NHA / 2	Elos Medtech Pinol A/S	Goerloese, DK	Lise Terkelsen
2026-10-01	K260029	Firstar Dental Handpieces	EFB / 1	FDC Technology Industry Co.	Kent, WA, US	David Yee
2026-10-01	K260027	Firstar Dental Electric Motor	EBW / 1	FDC Technology Industry Co.	Kent, WA, US	David Yee
2026-10-06	K260136	Forza	LRK / 2	True Function Laboratory, Inc.	La Mesa, CA, US	Frank Madrigal
2026-10-07	K262378	Dr.AlignNavi	PNN / 2	InnoDtech, Inc.	Gwangju, KR	Hyeon gu Lee
2026-10-08	K263680	One Coat Bond; One Coat Bond SL	KLE / 2	Dent4You AG	Heerbrugg, CH	Oliver Ashe
2026-10-09	K260096	Wishbone HAE	NPM / 2	Wishbone SA	Flémalle, BE	Caroline Trus
2026-10-09	K260913	CMF Titanium Splints	DZJ / 2	Materialise NV	Leuven, BE	Zarifa Mustafayeva

Gastroenterology, Urology (20)

Who should care: Endoscopy suppliers, GI/urology practices

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-12	K260133	CADDIE	QNP / 2	Odin Medical Limited	London, GB	Luke Sampson
2026-09-14	K253481	colonic FTRD Set (200.70); diagnostic FTRD Set (200.76); gastroduodenal FTRD Set (200.72)	PKL / 2	Ovesco Endoscopy AG	Tuebingen, DE	Antonio Caputo
2026-09-15	K261447	CVAC® Aspiration System	FGB / 2	Calyxo, Inc.	Pleasanton, CA, US	Joseph Catanese III
2026-09-16	K261913	X°Port Heart Preservation System	MSB / 2	Traferox Technologies, Inc.	Mississauga, CA	Anuradha Iyer
2026-09-16	K261400	Ambu® aScope□ Gastro; Ambu® aScope□ Gastro Large	FDS / 2	Ambu A/S	Ballerup, DK	Martina Krautwald

2026-09-17	K262913	Protégé□ EverFlex□ Self-expanding Peripheral Stent System	FGE / 2	Medtronic, Inc.	Plymouth, MN, US	Kim Wallner
2026-09-18	K262262	Pathfinder Endoscope Overtube	FED / 2	Neptune Medical, Inc.	Burlingame, CA, US	Alex Tilson
2026-09-18	K254179	Drainage Catheter	FGE / 2	Canyon Medical, Inc.	Nanjing, CN	Huiqi Jiang
2026-09-21	K262547	KARL STORZ TIPCAM1 Rubina	OWN / 2	KALR STORZ SE & Co. KG	Tuttlingen, DE	Winkie Wong
2026-09-21	K260512	Disposable Ureteral Access Sheath	FED / 2	Yangzhou Fartley Medical Instrument Technology Co., Ltd.	Yangzhou, CN	Xi Han
2026-09-23	K262353	BTL-299-F	KPI / 2	BTL Industries, Inc.	Marlborough, MA, US	David Chmel
2026-09-23	K261418	Liquick X-treme, Liquick X-treme Plus	EZD / 2	Teleflex Medical	Athlone, IE	Aisling Foley
2026-09-25	K254230	CapsoView (CVV); CapsoCloud (CLD)	QZF / 2	CapsoVision, Inc.	Saratoga, CA, US	Azimun Jamal
2026-09-30	K262038	danumed StomaMeter	KNT / 2	Danumed Medizintechnik GmbH	Regensburg, DE	Helena Bastian
2026-09-30	K262621	Rapid Barostat Bag (RBB) Pump and Catheter System	FFX / 2	Mui Scientific, Inc.	Mississauga, CA	Fatemeh Rahimi
2026-10-02	K261783	Plenity-V (MC0979 / GS110)	QFQ / 2	Gelesis SRL	Calimera, IT	Giorgio Sorcini
2026-10-02	K261791	MEDIVATORS□ ADVANTAGE NXT□ Automated Endoscope Reprocessor	FEB / 2	Steris	Mentor, OH, US	Steve Elliott
2026-10-02	K261741	Hemostatic Clip	PKL / 2	Anrei Medical (Hz) Co., Ltd.	Hangzhou, CN	Huibing Yang
2026-10-02	K260487	stentFIX System Set (100.50n)	PKL / 2	Ovesco Endoscopy AG	Tuebingen, DE	Nikol Gross
2026-10-06	K261141	OpenFlo Urinary Catheter	EZL / 2	Urolution Medical, Inc.	Maple Grove, MN, US	Darin Busch

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-15	K260145	YJ-K1K2 Wheelchair (YJ-013F)	IOR / 1	Zhenjiang Assure Medical Equipment Co., Ltd.	Zhenjiang City, CN	Mei Ying
2026-09-15	K260144	Reclining wheelchair (YJ-013L)	IOR / 1	Zhenjiang Assure Medical Equipment Co., Ltd.	Zhenjiang City, CN	Mei Ying
2026-09-15	K260141	Bariatric Heavy Duty Wheelchair (YJ-010V, YJ-010C)	IOR / 1	Zhenjiang Assure Medical Equipment Co., Ltd.	Zhenjiang City, CN	Mei Ying
2026-09-16	K262054	Electric Wheelchair	ITI / 2	Yongkang Joymax Medical Technology Co., Ltd.	Yongkang, CN	Sufiya Dong
2026-09-16	K261919	Multifunctional wheelchair (YJ-059)	IOR / 1	Zhenjiang Assure Medical Equipment Co., Ltd.	Zhenjiang, CN	Christine Dong
2026-09-19	K261859	Electric Scooter (FDB08, FDB08A, FDB12)	INI / 2	Anhui JBH Medical Apparatus Co., Ltd.	Chuzhou, CN	Yuanwei Wei
2026-09-22	K253762	ErgoSteel (ES0001/696)	IOR / 1	Strongback Mobility AG C/O Blueaudit GmbH	Pfaffikon, CH	Roman Hefle
2026-09-23	K262582	Electric wheelchair (GP100)	ITI / 2	Suzhou Green Pine Medical Co., Ltd.	Suzhou, CN	Guohua Wu
2026-09-23	K262254	Hair Growth Comb (X-GC01)	OAP / 2	Guangdong Ashmore Health Technology Co., Ltd.	Foshan, CN	Guangchao Xu
2026-09-24	K262183	Hair Growth Helmet (TK-176, TK-600, TK-500, TK-282, TK-	OAP / 2	Shenzhen Nuon Medical	Shenzhen, CN	Alain Dijkstra

		500A, TK-282A, TK-126, TK-60)		Equipment Co., Ltd.		
2026-09-24	K261078	Electric Scooter (FNS01,FNS03)	INI / 2	Anhui Jbh Medical Apparatus Co., Ltd.	Chuzhou, CN	Yuanwei Wei
2026-09-29	K262241	Electric Wheelchair (0080)	ITI / 2	Xuzhou Heabens Medical Technology Co., Ltd.	Xuzhou, CN	Eric Wang
2026-09-29	K262213	Power Mobility Scooter (MA03)	INI / 2	Nanjing Mijo Technology Co., Ltd.	Nanjing, CN	Leo Zhang
2026-09-29	K262553	MOBILITY SCOOTER (YQ-401,YQ-401A,YQ-403,YQ-403A)	INI / 2	Zhejiang Kailang Technology Co., Ltd.	Yongkang, CN	Yongda Mei Mei
2026-10-05	K262812	Air compression massager (ACM-C1, ACM-C2, ACM-C3, ACM-C4, ACM-C5, ACM-C6, ACM-C7, ACM-C8, ACM-C9, ACM-5C1, ACM-5C2, ACM-5C3, ACM-5C4, ACM-5C5, ACM-5C6, ACM-5C7, ACM-5C8, ACM-5C9)	IRP / 2	Sichuan Qianli-Beoka Medical Technology, Inc.	Chengdu, CN	qiuju Cai
2026-10-06	K261079	Power Wheelchair (DC12)	ITI / 2	Anhui JBH Medical Apparatus Co., Ltd.	Chuzhou, CN	Yuanwei Wei
2026-10-06	K261200	Power Wheelchair (D60)	ITI / 2	Anhui JBH Medical Apparatus Co., Ltd.	Chuzhou, CN	Shifu Yan
2026-10-06	K261887	Normatec Elite Heat (PRO26-SH);Normatec Elite Heat (PRO26-ST);Normatec Elite Heat (PRO26-TL);Normatec Elite Heat (PRO26-PH);Normatec Elite Heat (PRO26-PS);Normatec Elite Heat (PRO26-PT)	IRP / 2	NormaTec Industries, LP	Watertown, MA, US	Steve Henderson

2026-10-09	K262834	Led and Laser Hair Growth Device (H5520, H5521, H5522, H5523, H5524, H5525, H5530, H5605, H5610, H5615, H5620, H5625, H5630, H6510, H6520, INIA-HM100, ID-FLH-500)	OAP / 2	Shenzhen Jianchao Intelligent Technology Co., Ltd.	Shenzhen, CN	Fred Li
------------	-------------------------	--	---------	--	--------------	---------

Microbiology (13)

Who should care: Diagnostics distributors, clinical labs

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-14	K262163	BD BBL Mueller Hinton II Broth (Cation-Adjusted); BD Difco Mueller Hinton Broth	JTZ / 2	Becton Dickinson and Company	Sparks, MD, US	Danielle Hilligoss
2026-09-22	K263054	BIOFIRE Respiratory Panel 2.1 (RP2.1)	QOF / 2	Biofire Diagnostics	Salt Lake City, UT, US	Daisy Ramos
2026-09-23	K262156	Anti-HCV Next	MZO / 2	Abbott Laboratories	Abbott Park, IL, US	Caroline Mendes
2026-09-24	K262168	QIAstat-Dx BCID GN Plus AMR Panel	PEN / 2	QIAGEN GmbH	Hilden, DE	Hina Patel
2026-09-25	K261336	Xpert Respiratory Panel	QOF / 2	Cepheid	Sunnyvale, CA, US	Suzette Chance
2026-09-28	K260619	VITEK 2 AST-Streptococcus Cefepime (≤ 0.06 $\square$ ≥ 4 $\mu\text{g/mL}$)	LON / 2	Biomérieux, Inc.	Hazelwood, MO, US	Esther Hernandez
2026-09-30	K263035	CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel (includes Influenza A/B Typing Kit, Influenza A Subtyping Kit, Influenza A(H5) Subtyping Kit, and Influenza B Lineage Genotyping Kit)	OZE / 2	Centers for Disease Control and Prevention	Atlanta, GA, US	Marie Kirby
2026-10-01	K260283	VITEK 2 AST-Streptococcus	LON / 2	bioMérieux, Inc.	Hazelwood, MO, US	Esther Hernandez

		Meropenem (=0.06 - =4 µg/mL)				
2026-10-02	K260221	Elecsys EBV EBNA IgG	LSE / 1	Roche Diagnostics	Indianapolis, IN, US	Linda McCammack
2026-10-02	K260232	Elecsys EBV VCA IgG	LSE / 1	Roche Diagnostics	Indianapolis, IN, US	Cynthia Aker
2026-10-02	K263120	Xpert Xpress CoV-2/Flu plus	QOF / 2	Cepheid®	Sunnyvale, CA, US	Suzette Chance
2026-10-02	K260233	Elecsys EBV IgM	LJN / 1	Roche Diagnostics	Indianapolis, IN, US	Cynthia Aker
2026-10-07	K262368	B. anthracis Real-time PCR Assay	NHT / 2	Centers for Disease Control and Prevention	Atlanta, GA, US	Jasmine Chaitram

Neurology (12)

Who should care: Neuro device suppliers, neurology practices, neurotech investors

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-15	K260446	Tontarra Punches and Rongeurs	HAE / 2	Tontarra Medizintechnik GmbH	Wurmlingen, DE	Andreas Birk
2026-09-16	K261370	LED Light Therapy Masks (LED Face Mask Pulse (FAC06NA))	NFO / 2	Guangdong Newdermo Biotech Co., Ltd.	Guangzhou, CN	JunYi Xing
2026-09-16	K261712	Ceribell EEG Analysis Software	OLT / 2	Ceribell, Inc.	Sunnyvale, CA, US	Raymond Woo
2026-09-17	K252995	Durashield Device Kit	GZT / 2	SurGenTec, LLC	Boca Raton, FL, US	Richard Sharp
2026-09-24	K263010	ISIS Headboxes, ISIS Neurostimulator, ISIS Xpert Plus, ISIS Xpert, ISIS Xpress	GWF / 2	inomed Medizintechnik GmbH	Emmendingen, DE	Johannes Hoerth
2026-09-30	K262257	Spine Planning (3.0); Spine & Trauma Navigation; Alignment System Spine	OLO / 2	Brainlab SE	Munich, DE	Esther Moreno Garcia
2026-10-02	K260064	Neurora	QPF / 2	Argus Cognitive, Inc.	Hanover, NH, US	Andrea Marosan

2026-10-02	K260044	Ventricular Catheters, Thomale Catheter	JXG / 2	Aesculap, Inc.	Center Valley, PA, US	Kathy Racosky
2026-10-02	K254030	cCeLL405	QFX / 2	VPIX Medical, Inc.	Daejeon, KR	Kyungmin Hwang
2026-10-08	K261805	NEXT-Cue	QWT / 2	Neuroxt, Inc.	Seoul, KR	Sunyoung Kim
2026-10-09	K261521	Sleep Analysis Module	OLZ / 2	Neurotronics, LLC	Alachua, FL, US	James Smith
2026-10-09	K263154	CarboClear® Cervical Navigated Instruments	OLO / 2	CarboFix Orhtopedics , Ltd.	Herzeliya, IL	Yael Rubin

Anesthesiology (9)

Who should care: Respiratory/anesthesia suppliers, hospital procurement

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-16	K260226	ElintMAX Respiratory Monitor (ElintMAX Monitor A1)	BZK / 2	Amptron Medical, Inc.	Carlsbad, CA, US	Nirav Patel
2026-09-18	K254171	Mesh Nebulizer (UN204); Mesh Nebulizer (UN205); Mesh Nebulizer (UN209); Mesh Nebulizer (UN210)	CAF / 2	Shenzhen Mericonn Technology Co., Ltd.	Shenzhen, CN	Chuanyuan Jiang
2026-09-23	K254289	Portable Oxygen Concentrator (OX-1A-E, OX-1B)	CAW / 2	Oxytek Medical Technology Co., Ltd.	Chencun Town, Shunde District, Foshan, CN	Jenny Liu
2026-09-24	K260949	Disposable Belts for Polysomnography (CNSAC)	MNR / 2	CNSAC Medshop GmbH	Theilheim, DE	Arash Kianian
2026-09-25	K261372	Profoject□ LOR Syringe	CAZ / 2	CMT Health PTE., Ltd.	Singapore, SG	Monica Ma
2026-09-25	K260140	Aevice Wheeze Detection Module	PHZ / 2	Aevice Health Pte. , Ltd.	Singapore, SG	Adrian Ang
2026-09-25	K261262	Altis Full Face Mask	BZD / 2	Respironics, Inc.	Murrysville, PA, US	Viralyne Lipps
2026-10-05	K261939	Glucommander	NDC / 2	Glytec, LLC	Greenville, SC, US	Rachel Hofmann

2026-10-11	K253717	Helo□ Return	CAC / 2	Endovascular Engineering, Inc.	Menlo Park, CA, US	Debra Cogan
------------	-------------------------	--------------	---------	--------------------------------	--------------------	-------------

Clinical Chemistry (8)

Who should care: Lab distributors, reagent suppliers, clinical labs

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-16	K261896	iOS CamAPS FX	QJI / 2	CamDiab	London, GB	Roman Hovorka
2026-09-18	K262599	Biolinq Shine Autonomous Time-in-Range Microsensor	SFU / 2	Biolinq Incorporated	San Diego, CA, US	Aly Alvarez
2026-09-21	K262109	Access NT-proBNP	NBC / 2	Beckman Coulter, Inc.	Chaska, MN, US	Beth Davis
2026-09-22	K262299	Instant-View® hCG Combo II Cassette Test	JHI / 2	Alfa Scientific Designs, Inc.	Powat, CA, US	Michael Chien
2026-09-25	K262215	Profoject□ Safety Sliding Blood Collection Set	JKA / 2	CMT Health PTE., Ltd.	Singapore, SG	Monica Ma
2026-10-02	K260689	CVS Advanced PLUS Blood Glucose Monitoring System	NBW / 2	I-Sens, Inc.	Seoul, KR	Jeong Soohyun
2026-10-02	K260468	H100Plus Hemoglobin Testing System	PDJ / 2	Shenzhen Lifotronic Technology Co., Ltd.	Shenzhen, CN	Xiang Lei
2026-10-09	K260687	VivaChek Blood Glucose and β-Ketone Dual BLE Monitoring System; VivaChek Blood Glucose and β-Ketone Dual Monitoring System.	NBW / 2	Vivachek Biotech (Hangzhou) Co., Ltd.	Hangzhou, CN	Mark Qian

Obstetrics/Gynecology (8)

Who should care: Women's-health distributors, OB/GYN practices

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-17	K254203	Wearable Breast Pump (Model S36)	HGX / 2	Shenzhen TPH Technology Co., Ltd.	Shenzhen, CN	Dale Wang

2026-09-18	K261102	UNIDRIVE Select System	HIH / 2	Karl Storz SE & CO. KG	Tuttlingen, DE	McElroy Alita
2026-09-21	K262108	FAMA Male Latex Condoms □ Aqueous Lubricant (Ultra-thin);FAMA Male Latex Condoms □ Aqueous Lubricant (Plain);FAMA Male Latex Condoms □ Aqueous Lubricant (Ribbed);FAMA Male Latex Condoms □ Aqueous Lubricant (Dotted);FAMA Male Latex Condoms □ Aqueous Lubricant (Non-regular Shaped);MO Male Latex Condoms □ Aqueous Lubricant (Ultra-thin);MO Male Latex Condoms □ Aqueous Lubricant (Plain);MO Male Latex Condoms □ Aqueous Lubricant (Ribbed);MO Male Latex Condoms □ Aqueous Lubricant (Dotted);MO	HIS / 2	Shanghai Personage Hygiene Products Co., Ltd.	Shanghai, CN	Zhengjun Zhu
2026-09-23	K260117	Everslide	NUC / 2	Special Situations, LLC	Tulsa, OK, US	Michael Frid
2026-09-24	K254303	KARL STORZ SUPRALOOP	KNF / 2	Karl Storz SE & CO. KG	Tuttlingen, DE, US	Mario Trujillo
2026-09-25	K254252	UNIDRIVE SIII System; HOPKINS Telescope 0° (26205AMA) Operating Sheath (26205CD) Obturator (26205OC) Shaver Blade (26205SA) Shaver Blade (26205SB) Shaver Blade (091133-01/-10) Shaver Blade (091134-01/-10)	HIH / 2	Karl Storz SE & CO. KG	Tuttlingen, DE	Alita McElroy
2026-10-09	K262090	Fertilis microICSI Device	MQK / 2	Fertilis Pty, Ltd.	Adelaide, AU	Roger Yerramsetti
2026-10-09	K261234	The D-Tip Denudation Pipette	MQH / 2	Allwin Medical Devices, Inc.	Anaheim, CA, US	Digish Mehta

General Hospital (7)

Who should care: Hospital supply chain/GPO, sterilization & disposables suppliers

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-17	K261266	MOWANA□ Auto Duo	FMI / 2	PENTAMASTER MEDIQ SDN BHD	Simpang Ampat, MY	Thean Lye Ong
2026-09-18	K262532	NORMOFLO□ Irrigation Fluid Warming Sets and Accessories (IR-601, IR-501, IR-61, PL-61)	LGZ / 2	ICU Medical	Lake Forest, IL, US	Luis Ramirez
2026-09-18	K254095	25G Huber Needle	PTI / 2	Martech Medical Products	Harleysville, PA, US	Ashley Rolfe
2026-09-25	K261992	3M□ Attest□ Steam Chemical Integrator (1243A, 1243B, 1243RE, 1243RES)	JOJ / 2	Solventum US, LLC	San Antonio, TX, US	Heidi Wallis
2026-10-01	K262208	Non-sterile, Powder Free Nitrile Examination Aloe Vera Green Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Simulated Gastric Acid;Non-sterile, Powder Free Nitrile Examination Gloves, Low Dermatitis Potential, Tested for use with Chemotherapy Drugs, Fentanyl Citrate and Simulated Gastric Acid □ Blue;Non-sterile, Powder Free Nitrile Examination Gloves - Pink	LZA / 1	Yty Industry (Manjung) Sdn Bhd	Sitiawan, MY	Punitha Samy
2026-10-06	K262516	TSK OptiXion	QYM / 2	Tsk Laboratory, Japan	Tochigi-Ken, JP	Yumi Ueda
2026-10-09	K260080	Pro-Line XL Power Injectable Central Venous Catheter	LJS / 2	Medical Components, Inc.	Harleysville, PA, US	Elizabeth Greene

		and Pro-Line XL Tunneler				
--	--	-----------------------------	--	--	--	--

Unknown (6)

Who should care: Distributors and suppliers in this specialty

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-16	K262559	Mouth Guard	OBR / U	ChangSha ChuangDuoLe E-Commerce Co., Ltd.	Changsha, CN	Wei Luo
2026-09-22	K254168	Actolind® (06.3637. Actolind® Gel Plus)	FRO / U	ACTO GmbH	Braunschweig, DE	Ahmet Kilic
2026-09-24	K262618	Arthrex Spine Compression FT Screw	MRW / U	Arthrex, Inc.	Naples, FL, US	Kristi Frisch
2026-09-27	K260945	Ultima System (UL-800);Ultimate Face Package (UL-800-Face-Set);Ultimate Shape Extension Kit 1 (UL-800-Shape-Ext-Kit-1);Ultimate Shape Extension Kit 2 (UL-800-Shape-Ext-Kit-2)	/	Fit-Pro KFT (Ltd.) - DBA E-Fit	Budapest, HU	Janos Papp
2026-09-29	K260031	THERMEO® I MSI	MQC / U	Pro3Dure Medical GmbH	Iserlohn, DE	Frank Gischer
2026-10-08	K262244	Sonopet iQ Series III Console (5700-050-000); Sonopet iQ+ Straight Handpiece (5500-260-000); Sonopet iQ+ 10mm iQ+ Blade (5500-26B-010); Sonopet iQ+ 20mm iQ+ Blade (5500-26B-020); Sonopet iQ+ 11cm iQ+ Apex Knife (5500-26B-114); Sonopet iQ+ 12cm iQ+ Apex 360 (5500-26B-312); Sonopet iQ+ 12cm iQ+ Claw (5500-26B-328)	LFL / U	Stryker Instruments	Portage, MI, US	Alison Garrad

Ear, Nose, Throat (4)

Who should care: ENT/hearing suppliers, audiology practices

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-15	K254299	CLEARVISION Irrigation Sheath 0° (7241AS); CLEARVISION Irrigation Sheath 30° (7241BS); CLEARVISION Irrigation Sheath 45° (7241FS)	EOB / 2	Karl Storz SE & CO. KG	Tuttlingen, DE	Jennifer Downing
2026-09-16	K260309	Ambu® aScope□ 5 Broncho 2.7/1.2; Ambu® aScope□ 5 Broncho 4.2/2.2; Ambu® aScope□ 5 Broncho 4.2/2.2 Sampler Set	EOQ / 2	Ambu A/S	Ballerup, DK	Karina Matthiesen
2026-09-21	K261725	OtoCompanion (Version 1.0)	SHL / 2	Ironsides Medical, Inc.	Cambridge, MA, US	Daphne Psacharopoulos
2026-09-23	K261637	Single-use Flexible Bronchoscope	EOQ / 2	Hunan Vathin Medical Instrument Co., Ltd.	Xiangtan, CN	Fei Lina

Hematology (2)

Who should care: Lab/blood-bank suppliers

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-14	K260781	Yumizen H550	GKZ / 2	HORIBA ABX SAS	Montpellier, FR	Christelle Calvo
2026-09-24	K260214	STA® - Liquid Anti-Xa	KFF / 2	Diagnostica Stago, Inc.	Parsippany, NJ, US	Louise Sigismondi

Ophthalmic (2)

Who should care: Optical/ophthalmic distributors, eye-care practices

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
------	----	--------	------------	-----------	----------	--------------------

2026-09-17	K262495	Miru 1day UpSide (midafilcon A)	LPL / 2	Menicon Co, Ltd.	Nagoya, JP	Kana Nagasaki
2026-09-18	K262637	SLIT LAMP SL-D4 (Type: LED)	HJO / 2	Topcon Corporation	Tokyo, JP	Tomoka Nishiyama

Immunology (1)

Who should care: Diagnostics distributors, clinical labs

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-30	K262893	Eonis [®] SMA kit	QUE / 2	Revvity, Inc.	Waltham, MA, US	Lisa Vershave

Pathology (1)

Who should care: Pathology labs, digital-pathology vendors

Date	K#	Device	Code/Class	Applicant	Location	Contact (as filed)
2026-09-25	K260023	TumorSight Risk	SHW / 2	SimBioSys, Inc.	Chicago, IL, US	Joseph Peterson

Data from openFDA; FDA states results should be assumed unvalidated. Contact names are as listed in public filings. Company domains not yet verified. Not regulatory advice.