



FDA/CDRH Office of Product Evaluation and Quality (OPEQ)

2025 DEVICE MARKETING ENFORCEMENT LETTERS

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|--------------------------|--|-------------|---|---|
| 1/21/2025 | Robbins Instruments, LLC | <p>Dermo-Jet Needleless Injector <i>The DERMO-JET is a versatile, time-tested, medical instrument for administration of sub-topical injections of parenteral medicaments, anesthetic solutions, steroids in aqueous suspension, soluble drugs, vaccines, antibiotics, etc.</i></p> | WL | Brochure | <p>Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval)</p> <p>Labeled without required UDI elements</p> |
| 2/5/2025 | Q'Apel Medical, Inc. | <p>072 Aspiration System and 072 Aspiration Catheter <i>As part of the 072 Aspiration System, the 072 Aspiration Catheter with a compatible suction pump is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.</i></p> <p>Aspiration Tubing <i>As part of the 072 Aspiration System, the Aspiration Tubing is intended to connect the</i></p> | WL | <p>Email</p> <p>Mechanism of Action Video</p> <p>Design History Notes</p> | <p>Marketed with design or technological modifications exceeding limits of existing FDA marketing authorization or premarket review exemption</p> |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|--------------------------|--|-------------|--------------------------------|---|
| | | <i>072 Aspiration Catheter to a compatible suction pump.</i> | | | |
| 2/10/2025 | Exer Labs, Inc. | Exer Scan <i>This device is registered under the Measuring Exercise Equipment Exemption, which applies to devices that are intended to provide or facilitate exercise rehabilitation and include exercise measurement capabilities.</i> | WL | Website | Marketed with claims exceeding limits of premarket review exemption |
| 2/21/2025 | Next Science LLC | SURGX <i>Next Science Wound Gel (Rx) is indicated for the management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first- and second-degree burns, grafted and donor sites.</i> BLASTX <i>Next Science Wound Gel is indicated for the management of skin abrasions, lacerations, minor irritations, cuts, exit sites and intact skin.</i> XPERIENCE <i>MIS Solution is indicated for use in cleansing and removal of debris, including microorganisms, from wounds.</i> | WL | Website Marketing Materials | Marketed with claims exceeding limits of existing FDA marketing authorization FDA previously communicated related concerns to firm |
| 2/21/2025 | Red Oak Instruments, LLC | RU-FIT (Model SR-3053) <i>The device is used in any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a</i> | WL | User Guide Presentation | Marketed with claims exceeding limits of existing FDA marketing authorization |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|----------------------|--|-------------|-----------------------|---|
| | | <p><i>person who has sustained an injury or suffered a disease of his/her hand(s).</i></p> <ul style="list-style-type: none"> <i>To measure grip or pinch strength in an injured and uninjured hand.</i> <i>To conduct pre-employment screening for physically demanding job activities.</i> <i>To establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace.</i> | | Website | Marketed with claims exceeding limits of premarket review exemption |
| 3/12/2025 | Rex Implants Inc. | <p>REX Mallet <i>This device is intended to exert force in a surgical setting.</i></p> <p>Rexpander <i>The rexpander device is intended to be used for alveolar ridge splitting including use of force to expand the bone.</i></p> <p>Piezol Implant REX BL 2.9 Implant System <i>The Piezol Implant System is intended for use in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible.</i></p> | WL | Website IFU | <p>Marketed with claims exceeding limits of existing FDA marketing authorization</p> <p>Marketed with design or technological modifications exceeding limits of existing FDA marketing authorization</p> <p>Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval)</p> |
| 3/31/2025 | DRG Instruments GmbH | <p>Salivary Cortisol ELISA <i>An enzyme immunoassay for the quantitative in vitro diagnostic measurement of active free cortisol (hydrocortisone and hydroxycorticosterone) in saliva.</i></p> | WL | Website IFU | Marketed with design or technological modifications exceeding limits of existing FDA marketing authorization or |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|-----------------------|--|-------------|-----------------------|---|
| | | <p><i>Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.</i></p> <p>Salivary Cortisol ELISA RUO <i>An enzyme immunoassay for the quantitative measurement of active free cortisol (hydrocortisone and hydroxycorticosterone) in saliva. This product is for Research Use Only.</i></p> | | | <p>Marketed Research Use Only device for clinical use</p> <p>Misrepresented device's regulatory status/marketing authorization (e.g., calling a device under an exemption "FDA approved")</p> <p>FDA previously communicated related concerns to firm</p> |
| 4/4/2025 | ICU Medical | <p>Medfusion Model 4000 Syringe Infusion Pump</p> <p>CADD Solis VIP Ambulatory Infusion Pump <i>These devices appear to be classified under the regulation pertaining to infusion pumps.</i></p> | WL | n/a | Marketed with design or technological modifications exceeding limits of existing FDA marketing authorization |
| 6/3/2025 | Inshitra Medical Inc. | <p>Double Pump and Ultra Intra Aortic Balloon Pump (IABP) Catheter Kits</p> <p><i>This device has the following indications for use: Refractory unstable angina; impending infarction; post infarction angina; refractory left ventricular failure; complications of Acute MI; cardiogenic shock; support for diagnostic, percutaneous revascularization and interventional procedures; ischemic related intractable ventricular arrhythmias; septic shock; Intraoperative pulsatile flow generation; weaning from cardiopulmonary bypass; cardiac support for non-cardiac surgery; prophylactic support in preparation for cardiac surgery; post-surgical myocardial</i></p> | WL | Labeling Website | <p>Marketed with claims exceeding limits of existing FDA marketing authorization</p> <p>Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval)</p> <p>FDA previously communicated related concerns to firm</p> |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|------------------------------|---|-------------|-----------------------|---|
| | | <i>dysfunction/low cardiac output syndrome; Cardiac contusion; mechanical bridge to other assist devices; cardiac support following correction of anatomical defects.</i> | | | |
| 6/9/2025 | Reset Technology Corporation | <p>ResetSmile Partial Denture Device <i>This device is a removeable dental appliance used to replace missing teeth.</i></p> <p>ResetSmile Impression Kit Device <i>This device is an impression kit used to help make the removeable dental appliance.</i></p> | WL | n/a | <p>Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval)</p> <p>Labeled without required UDI elements</p> |
| 6/27/2025 | Mectronic Medicale S.R.L. | <p>Doctor Tecar <i>The Doctor Tecar device is intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as relief of pain, muscle spasms, and increase in local circulation.</i></p> <p>Doctor Tecar Smart and Doctor Tecar Plus <i>Doctor Tecar Plus and Doctor Tecar Smart devices are intended to provide topical heating for the purpose of elevating tissue temperature for treatment of selected medical conditions such as: relief of pain, muscle spasms, increase in local circulation.</i></p> <p>CHELT, Ixyon XP, iLux Smart, iLux Plus <i>These devices appear to be classified under the regulation pertaining to infrared lamps.</i></p> | WL | Marketing Materials | <p>Marketed with claims exceeding limits of existing FDA marketing authorization</p> <p>Marketed with claims exceeding limits of premarket review exemption</p> <p>Marketed with design or technological modifications exceeding limits of premarket review exemption</p> <p>Marketed without required electronic products reports and labels</p> |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|----------------------|---|-------------|----------------------------|---|
| 7/14/2025 | WHOOP, Inc. | Blood Pressure Insights <i>This device appears intended for users to measure or estimate their blood pressure.</i> | WL | Website Article | Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval) FDA previously communicated related concerns to firm |
| 7/22/2025 | Spectra Therapy, LLC | LASERwrap system includes the Spectra A-100 Impulse Laser Unit and accessories <i>This device appears to be classified under the regulation pertaining to infrared lamps.</i> Spectra Therapy Spectra A1000 <i>This device is intended to provide topical heating . . . [and] is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.</i> | WL | Website User Manual | Marketed with claims exceeding limits of premarket review exemption Marketed with claims exceeding limits of existing FDA marketing authorization Labeled without required UDI elements |
| 7/30/2025 | Les Encres LLC | Les Encres absorbable polydioxanone (PDO) surgical suture devices <i>Barbed suture comprised of dyed polydioxanone (PDO) is indicated for use in soft tissue approximation where use of absorbable suture is appropriate.</i> | WL | Website Product Listing | Marketed with claims exceeding limits of existing FDA marketing authorization |
| 7/30/2025 | Uscom Kft | SpiroThor (also marketed as mSpirometer or mSpiro) <i>SpiroThor spirometer is a freestanding laboratory instrument for performing basic lung function tests in adults and children over the age of four years. It is intended to be</i> | WL | n/a | Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval) FDA previously communicated related concerns to firm |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|-------------------------------|--|-------------|-----------------------|--|
| | | <p><i>used by physicians or professional medical personnel for testing in physicians' offices, industrial medical, and hospital settings.</i></p> <p>Spirosonic, SpiroSonic AIR, SpiroSonic FLO, and SpiroSonic SMART <i>The SpiroSonic spirometers are a freestanding laboratory instrument for performing basic lung function tests in adults and children over the age of four years. SpiroSonic AIR spirometer use Bluetooth and a phone app to display and transfer data that is intended for testing in physicians' offices, industrial medical, hospital and home settings.</i></p> | | | |
| 8/21/2025 | SeniorLife Technologies, Inc. | <p>SeniorLife.AI <i>The device is registered under the Measuring Exercise Equipment intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity.</i></p> | WL | Website | <p>Marketed with claims exceeding limits of premarket review exemption</p> <p>Misrepresented device's regulatory status/marketing authorization (e.g., calling a device under an exemption "FDA approved")</p> <p>Used FDA logo in promotional materials</p> |
| 8/25/2025 | The Richline Group, Inc. | <p>Inverness Ear Care Antiseptic and Inverness Ear Care Solution <i>These devices appear regulated as wound washes.</i></p> <p>Inverness Home Ear Piercing Kit</p> | WL | n/a | <p>Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval)</p> <p>FDA previously communicated related concerns to firm</p> <p>Labeled without required UDI elements</p> |

| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|-------------------------------|--|---|-------------|--|--|
| 9/18/2025 | LifeVac, LLC | LifeVac Rescue Suction Device <i>Airway clearance device used for resuscitating a victim with an airway obstruction when current choking protocols have been followed without success</i> | WL | Website Marketing Materials | Marketed without required FDA premarket review (i.e., Class II or III device lacking clearance or approval) FDA previously communicated related concerns to firm |
| 9/26/2025 | Technological Medical Advancements LLC | Diowave 100 WLS Diowave 250 WLS <i>The Diowave Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.</i> | WL | Website Physician Brochure AI Instructions for Use Diowave Life Without Pain Brochure Operating Manual | Marketed with claims exceeding limits of premarket review exemption Marketed with design or technological modifications exceeding limits of premarket review exemption Labeled without required UDI elements |
| 12/16/2025 | Trans-Missie B.V. | Breast Binders | WL | Website | Marketed without compliance with device listing or facility registration requirements (i.e., 510(k)-exempt device lacking listing) |
| 12/16/2025 | Philadelphia 7, Inc d/b/a Passional Boutique | | | | |
| 12/16/2025 | For Them, Inc. | | | | |
| 12/16/2025 | TOMSCOUT | | | | |
| 12/16/2025 | Early to Bed, Inc. | | | | |
| 12/16/2025 | FLAVNT Streetwear, LLC | | | | |
| 12/16/2025 | TomboyX, PBC | | | | |
| 12/16/2025 | GenderBender LLC | | | | |



| Date (Hyperlink to Letter) | Manufacturer | Device Indication(s) (As Referenced in Letter) | Letter Type | Form of Communication | Alleged Promotional or Marketing Violations |
|--------------------------------------|---|--|--------------------|------------------------------|--|
| 12/16/2025 | Marli Washington Design, LLC | | | | |
| 12/16/2025 | ShapeShifter Apparel, LLC | | | | |
| 12/16/2025 | Flux Lab Pte. Ltd. d/b/a The Fluxion | | | | |
| 12/16/2025 | TG Supply LLC d/b/a TransGuy Supply | | | | |