October 31, 2022

Actuated Medical, Inc
Douglas Dillon
Director, Quality Assurance & Regulatory Affairs
310 Rolling Ridge Drive
Bellefonte, Pennsylvania 16823

Re: K220890
Trade/Device Name: IO Needle Safety Sheath
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 28, 2022
Received: September 29, 2022

Dear Douglas Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Alan M. Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220890

Device Name
IO Needle Safety Sheath (IOSS)

Indications for Use *(Describe)*

The IO Needle Safety Sheath (IOSS) is intended to assist in the safe removal of intraosseous needles.

IOSS is Indicated for Use with 25mm and 45mm EZ-IO Vascular Access Needles and BD Luer-Lok 10mL Syringes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K 220890 510(k) SUMMARY

Applicant Information

Date Prepared: October 28, 2022

Name and Address: Actuated Medical, Inc.
320 Rolling Ridge Drive
Bellefonte, PA 16823
Ph: (814) 355-0003
Fx: (814) 355-1523

Contact Person: Douglas R. Dillon
Director, Quality Assurance and Regulatory Affairs
Ph: (814) 355-0003 x107
Fx: (814) 355-1523
Email: Douglas.Dillon@actuatedmedical.com

Device Information

Trade Name	IO Needle Safety Sheath (IOSS)
Common Name:	IO Needle Safety Sheath (IOSS)
Classification:	21 C.F.R. §880.5570
Classification Name:	Needle, Hypodermic, Single Lumen
Product Code:	FMI

Predicate Device

The legally marketed device to which substantial equivalence is being claimed:

510(k) Number	Trade Name	Submitter
K180395	EZ-IO Intraosseous Vascular Access System (EZ-IO)	Arrow International, Inc. (Subsidiary of Teleflex)

Device Description

The IO Needle Safety Sheath (IOSS) is a single-use, non-sterile, anti-needlestick accessory to assist in the removal of intraosseous (IO) needles. IOSS is placed around the syringe and IO needle prior to removal from the patient. It irreversibly captures the IO needle within the device upon removal from the patient; helping to prevent accidental needle sticks to the patient or user. There is tactile confirmation of capture, and the clear body of IOSS allows for visual confirmation that the IO needle is in Safe Mode.

Intended Use

IOSS is intended to assist in the safe removal of intraosseous needles.

Indications for Use

The IO Needle Safety Sheath (IOSS) is intended to assist in the safe removal of intraosseous needles. IOSS is indicated for use with 25mm and 45mm EZ-IO® Vascular Access Needles and BD Luer-Lok™ 10 mL Syringe.

Technological Characteristics

Because IOSS is only used to remove the parent predicate device (EZ-IO) from the patient, substantial equivalence considerations are primarily focused on the removal of EZ-IO as compared to the removal of EZ-IO with IOSS. The contraindications, target population, and anatomical sites used are identical to the predicate device. Key differences between the predicate and IOSS include needle removal technique, required accessories, sterility, patient contact, and materials of construction.

Category	Predicate EZ-IO	Proposed IOSS Used as Indicated with Predicate Device	Comparison
Indications for Use	For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases for up to 24 hours. Insertion sites: ADULTS (≥22 years old): proximal humerus, proximal tibia, distal tibia. PEDIATRICS (≤21 years old): proximal humerus, proximal tibia, distal tibia, distal femur. Use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established. Insertion sites: ADULTS (≥22 years): proximal humerus, proximal tibia, distal tibia. PEDIATRICS (≥12 years through 21 years old): proximal humerus, proximal tibia, distal tibia, distal femur.	The IO Needle Safety Sheath (IOSS) is intended to assist in the safe removal of intraosseous needles. IOSS is Indicated for Use with 25 mm and 45 mm EZ-IO® Vascular Access Needles and BD Luer-Lok™ 10 mL Syringes.	Different – Indications for the same intended use and a subset of the available needle sets does not raise new questions of safety or efficacy.

Category	Predicate EZ-IO	Proposed IOSS Used as Indicated with Predicate Device	Comparison
Needle removal technique	Remove any extension sets and dressings. Attach a luer-lock syringe to the hub of the catheter. While maintaining alignment of the needle and the syringe, the syringe is rotated clockwise while pulling straight up. Rocking or bending the catheter upon removal should be avoided.	Remove any extension sets and dressings. Attach a BD Luer-Lok 10 mL Syringe to the hub of the catheter. Latch IOSS around the syringe. Hold IOSS in place with one hand. While maintaining alignment of the needle and the syringe, the syringe is rotated clockwise while pulling straight up until the EZ-IO hub locks in Safe Mode. Rocking or bending the catheter upon removal should be avoided.	Different – Adding the use of IOSS into the removal process is a difference. It does not raise new questions of safety or efficacy.
Disposal	Dispose of the catheter with the syringe attached in an approved sharps container.	Dispose of catheter with the syringe attached and covered by IOSS immediately after use in an approved sharps container.	Same
Required accessories	Luer-lock syringe (not included) to use as handle for removal of needle.	IOSS indicated only for one specific syringe: BD Luer-Lok™ 10 mL Syringe (not included) to use as handle for removal of needle.	Same
Contra-indications	• Fracture in target bone. • Previous, significant orthopedic procedure at the site, prosthetic limb or joint. • IO access (or attempted IO access) in targeted bone within past 48 hours. • Infection at the area of insertion. • Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks.	Unchanged	Same

Category	Predicate EZ-IO	Proposed IOSS Used as Indicated with Predicate Device	Comparison
Target population	Adult and pediatric patients who are in need of vascular access.	Unchanged	Same
Where used	Pre-hospital In hospital Acute care	Unchanged	Same
Anatomical sites used	Proximal Humerus Proximal Tibia Distal Tibia Distal Femur (pediatrics only)	Unchanged	Same
Needle/ Cannula design	Sterile, single use Hubs: colored polycarbonate Stylet/catheter: Stainless Steel Faceted tip Standard luer connection Three lengths: 15 mm; 25 mm; 45 mm Size: 15 gauge (0.071", 1.8 mm) Needle Cover: Polypropylene	Device has no needle/cannula.	Different – IOSS assists in the safe removal intraosseous needles.
Needle set guidelines	Available Needle Sets: 15 mm: 3-39 kg 25 mm: 3 kg or over 45 mm: 40 kg or over	Indicated for Needle Sets: IOSS only indicated for the 25 mm and 45 mm Needle Sets	Different - IOSS only indicated for the 25 mm and 45 mm Needle Sets due to 15 mm Needle design.
Depth control	Positioning marks at 5 cm and 10 cm apart to provide visual reference points Tactile feedback for change of pressure	Unchanged.	Same
Single use components/ accessories	EZ-IO Needle Sets EZ-Connect Extension Set EZ-IO Patient Wristband EZ-Stabilizer Dressing	BD Luer-Lok™ 10 mL Syringe	Different – IOSS only requires a syringe for use.
Sterility	Sterile: Ethylene Oxide	IOSS is non-sterile.	Different – Patient contact for IOSS does not require sterilization.

Category	Predicate EZ-IO	Proposed IOSS Used as Indicated with Predicate Device	Comparison
Shelf life	4 Years	5 years	Different – Additional year of shelf life does not raise new questions of safety or efficacy.
Bio-compatibility	Biocompatible materials used (per ISO 10993-1 prolonged contact duration).	Biocompatibility of IOSS established per ISO 10993-1 for limited duration surface contact: Cytotoxicity, Sensitization, Irritation, Pyrogenicity, and Systemic Toxicity	Different – IOSS and Predicate both meet biocompatibility endpoints appropriate for their patient contact.
Materials of construction	Stainless steel catheter, polycarbonate and color additive hubs, and polypropylene needle cover.	Clear, colorless, INEOS K-Resin KR01 styrene butadiene block copolymer	Different – different materials meet all requirements for biocompatibility and physical properties; raising no new questions of safety or efficacy.

Non-Clinical Performance Data

The methods and performance data for evaluating the technological differences, the questions of safety and effectiveness, as well as IOSS integrity and compatibility with the predicate device (EZ-IO) include bench performance testing, usability testing, and biocompatibility testing.

Bench Performance Testing: Verification of Product Specification testing confirmed that the IO Needle Safety Sheath (IOSS) met all product specifications and acceptance criteria in ambient, high temperature/humidity, and low temperature environmental conditions. Distribution testing conforming to ISTA 3A 2018 (FDA Recognition Number

5-126) confirmed that IOSS met all product specifications and acceptance criteria after being exposed to shipping and transportation conditions. Accelerated Shelf Life testing confirmed that IOSS met all product specifications and acceptance criteria after exposure to conditions simulating a shelf life of up to 5 years.

Test Performed	Test Description	Standards Organization and Designation	Results
Biocompatibility	Final, finished devices tested for cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, and material mediated pyrogenicity.	ISO 10993-12, 2021 ISO 10993-5, 2009 ISO 10993-10, 2010 ISO 10993-23, 2021 ISO 10993-11, 2017	Pass
Verification of Product Specification	Verification of Product Specifications after exposure to ambient, high temp/humidity, and low temperature environmental conditions.	NA	Pass
Usability	A total of 500 uses by thirty (30) Users to assess whether the intended user population can use IOSS without encountering a needle stick, serious use errors, or problems for the intended use and expected use environment.	NA	Pass
Distribution	Confirmation of Product Specifications following exposure to simulated distribution stress and conditions.	ISTA 3A 2018	Pass
Accelerated Shelf Life	Confirmation of Product Specifications following exposure accelerated conditions simulating a shelf life of one (1), three (3), and five (5) years.	NA	Pass
Shelf Life	Confirmation of Product Specifications following real-time ambient condition exposure for one (1), three (3), and five (5) years.	NA	Test on-going.

Usability Testing: Human factors validation testing confirmed that the user population can safely and effectively use IOSS for the intended use in the expected use environment without encountering a needle stick, serious use errors, or other problems.

Biocompatibility Testing: IOSS is categorized as a limited duration surface device expected to normally contact intact skin, but which may incidentally contact breached or compromised skin. Cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity testing was conducted on IOSS in its final finished form. All tests confirmed the suitability of IOSS.

Conclusions

After evaluating IOSS for its intended use with EZ-IO (the predicate device), then identifying, evaluating, and mitigating the risks associated with both use and foreseeable misuse where practicable, and confirming the safety and effectiveness of the device was through worst-case testing, it is concluded that IOSS is as safe and effective as EZ-IO when used as indicated to remove EZ-IO 25 mm and 45 mm intraosseous needles.