November 21, 2019

SAM® Medical Products, Inc.
℅ Michelle Lott
Senior RA & QA Consultant
Lean RAQA, LLC
12602 North Summerwind Drive
Marana, Arizona 85658

Re: K191488
Trade/Device Name: SAM IO Intraosseous Access System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: October 24, 2019
Received: October 28, 2019

Dear Michelle Lott:

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,

For Alan 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191488

Device Name
SAM IO™ Intraosseous Access System

Indications for Use *(Describe)*
The SAM IO™ Intraosseous Access System provides Intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary: K191488

GENERAL INFORMATION

Submitted by:

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Date Prepared: November 20, 2019

Trade Name: SAM IO™ Intraosseous Access System

Common Name: Intraosseous Infusion System

Classification name: Needle, Hypodermic, Single Lumen

Regulation name: Hypodermic single lumen needle

Classification: Class II

Product Code: FMI

Regulation Number: 880.5570

Predicate Device: EZ-IO® Intraosseous Infusion System, Vidacare Corporation (now owned by Teleflex, Inc. (K141117)

DEVICE DESCRIPTION:

The SAM IO™ Intraosseous Access System consists of a single use disposable intraosseous (IO) needle assembly (the SAM IO™ Needle Set) that connects to a reusable manually powered drill (the SAM™ IO Driver). Upon manual activation, the Driver penetrates through the cortex of the bone to a desired depth within the bone marrow by means of rotary cutting action along with force applied axially by the operator. The Driver can then be separated from the hub of the IO needle assembly, leaving the cannula securely seated in the bone. The stylet containing the driver connection is then removed. The needle insertion can also be performed by hand without the use of the Driver as per the user's discretion. A standard Luer lock (part of the needle assembly) permits attachment of standard syringes and IV lines for administration

of drugs and fluids. Typical user profiles include Hospitals, Clinics, Physicians, Military, Medics, Nurses, EMTs (Emergency Medical Technicians).

INTENDED USE:

The SAM IO™ Intraosseous Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

The proposed system is indicated for Rx (prescription) use.

LABELING AND TECHNOLOGICAL CHARACTERISTICS COMPARISON:

As shown in Table 6-1 (see next page), the proposed SAM IO™ Intraosseous Access System has **identical** intended use and **similar** technology characteristics to the currently marketed EZ-IO® Intraosseous Infusion System (K141117).

Table 6-1: Comparison table

		Proposed system	Predicate system
Device Proprietary Name		SAM IO™ Intraosseous Access System	EZ-IO® Intraosseous Infusion System
Manufacturer		SAM® Medical Products, Inc.	Vidacare Corporation (now owned by Teleflex, Inc.)
510(k)		K191488	K141117
1. LABELING			
Class.	**Regulation**	21 CFR 880.5570	Same
	Product Code	FMI	Same
	Class. Name	Needle, Hypodermic, Single lumen	Same
Intended use		The SAM IO™ Intraosseous Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.	The EZ-IO® Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.
Indication for use	**Rx or OTC**	Rx	Same
	Target population	Adult and pediatric patients who are in need of vascular access.	Same
Contraindications		Fracture in targeted bone	Same
		Previous, significant orthopedic procedure at site selected for insertion	Same
		Intraosseous catheter placement in targeted bone within past 48 hours.	
		Infection at site selected for insertion	Same
		Excessive tissue or absence of anatomic landmarks	Same
		Not for sternal use	Same
Labels		Different labels for each needle size. Include relevant symbols and warnings. Identify specification for patient's weight.	Equivalent, predicate labeling contains appropriate symbols and warnings.
Instructions for Use (IFU)		Step-by-step procedure to establish IO access. One (1) IFU document for the Needle Set & Accessories and one (1) IFU document for the Driver.	Equivalent, IFU includes the same critical tasks and only differs by information specific to the predicate system.
2. TECHNOLOGY			
Use Environment (Where used)		Emergency settings: Pre-hospital, In hospital, Acute care, Military	Same
Anatomical sites used		Four (4) insertion sites • Proximal tibia • Distal tibia • Humeral head (proximal humerus) • Distal femur (pediatric patients only)	Same

	Proposed system	Predicate system
IO insertion depth assessment	• Tactile feedback for change of pressure • Depth indicator markings on cannula to provide visual reference points	Same
Clinical decisions to make by clinicians	• Decision to use IO access instead of IV access • Insertion site selection, anatomical landmarks identification and site preparation • Needle size selection • Determination of depth of tissue overlying the bone and the distance needed to adequately pass into medullary bone • Decision to insert with or without using the driver	Same
Time to establish IO access in *in-vitro* model	Less than 10 seconds	Same
Mode of action	The user inserts the needle set assembly through the cortex of the bone to a preset depth within the bone marrow (with or without using the driver). Once the cannula is securely seated in the bone, the stylet is removed and a standard Luer lock (part of the needle assembly) then permits attachment of standard syringes and IV lines for administration of drugs and fluids.	Same
Possibility to use manual insertion (*i.e.* without using the driver)	Yes	Same
2.a) Needle Set & Accessories		
Sterile single use components / accessories	System includes: • Needle sets • Extension Tubing Set • 1-port Sharps Block	Same
Needles length offered	15, 25, 45mm	Same
Needles OD	15 gauge (G) for all lengths	Same
Needle tip shape	Double diamond stylet tip, 5-point crown cannula tip	Equivalent – Faceted, a patented cutting tip with a match ground cannula tip
Stylet use	Yes	Same
IV lines connection	Standard Luer connection	Same
Needle set guidelines and corresponding hubs colors	Available needle sets: • 15 mm: 3-39 kg (pink hub) • 25 mm: 3 kg or over (blue hub) • 45 mm: 40 kg or over, excessive tissue, humerus (yellow hub)	Same
Depth indicator markings on cannula	• 15 mm: 1 marking • 25 mm: 2 markings • 45 mm: 4 markings Black indicator lines are located at 5 mm increments from the hub for assessing insertion depth.	Same
Shelf life	12 months (1 year)	4 years
Sterility	Ethylene Oxide (EO), SAL 10^{-6}	Same
Biocompatibility	Meets ISO 10993-1 for a device contacting Tissue/Bone/Blood (Intraosseous) for a limited duration (≤ 24h)	Same
2.b) Driver		
Weight	~75g	~300g
Dimensions	• Back handle to trigger: 80mm • Top to bottom: 105mm	• Back handle to trigger: 70mm • Top to bottom: 105mm
Design	The SAM IO™ Driver is a reusable manually operated drill connected to a disposable IO needle assembly.	The EZ-IO® Power Driver (which looks similar to a cordless drill) consists of a reusable battery powered rotational driver connected to a disposable IO needle assembly.
	Hand-held, cordless drilling device	Same
Mode of action	Upon manual activation, the drill penetrates through the cortex of the bone to a preset depth within the bone marrow.	Same

	Proposed system	Predicate system
	The driver then separates from the hub of the IO needle assembly, leaving the cannula securely seated in the bone.	Same
	The trocar stylet that acts as the drill bit is then removed.	Same
Source of power	Manual	Sealed lithium battery not intended to be opened. Battery is not replaceable.
Sterility	Sold non-sterile	Same
Biocompatibility	Contact intact skin only. To be used with gloves.	Same
Reuse instructions	Reusable as per IFU instructions	Same
Prior to use	Inspection required to verify normal operation	Same
Materials	Polycarbonate, stainless steel, santoprene, medical grade silicone lubricant.	Injection molded rigid polymer (unknown material likely polycarbonate or ABS), thermoplastic elastomer, electromagnetic drive mechanism

Discussion of Differences

Technological differences are mainly due to the fact that the proposed system includes a manually operated driver whereas the predicate includes a battery-powered driver and that the interface between the needle and the drilling device has a different shape (pentagonal *vs.* hexagonal) and a different type of attachment mechanism (magnetic *vs.* snap-in). In addition, there are differences in weight and dimensions of the drilling device. These differences were addressed through simulated use testing and non-clinical comparative testing.

In addition, the needle tip geometry is different. However, non-clinical comparative testing was provided to ensure penetration capabilities were the same and testing per ISO standards (See Table 6-2) ensures it meets the same standards as the predicate.

The differences identified do not raise different question of safety and effectiveness.

NON-CLINICAL TESTING

Performance (Bench) Testing: Performance bench testing was conducted to ensure that the SAM IO™ Intraosseous Access System met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate system. The following performance testing was performed or fulfilled with the SAM IO™ Intraosseous Access System.

Table 6-2: Summary of performance standards

Performance Standards		
Standard ID #	**Title**	**Conclusion**
ISO 80369-7 (1st edition 2016-10-15)	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	Fulfilled (as per Argon's 510k K980196)
ISO 23908 (1st edition 2011-06-11)	Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	Passed-Fulfilled
ISO 7864 (4th edition 2016-08-01)	Sterile hypodermic needles for single use - Requirements and test methods	Passed-Fulfilled
ISO 9626 (2nd edition 2016-08-01)	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods	Passed-Fulfilled
ISO 10555-1 (2nd Edition 2013-06-15)	Intravascular catheters - Sterile and single-use intravascular catheters - Part 1: General requirements	Fulfilled (2X EO Exposure prior to testing)
ASTM A632-04 (2004)	Standard specification for Seamless and Welded Austenitic Stainless Steel Tubing (small-diameter) for general service	Fulfilled (as per CoC's)
ASTM A313-13 (2013)	Standard Specification for Stainless Steel Spring Wire	

Comparative testing: The functions of the subject system that are equivalent to the predicate system have been subjected to comparative testing to ensure that the subject system performs these functions without raising different questions of safety and effectiveness.

Simulated use: Simulated use results provided by SAM® Medical Products, Inc. support the conclusion that the proposed device is clinically safe for prescription use. Furthermore, SAM® Medical Products, Inc. conducted a risk analysis on the proposed system in accordance with ISO 14971:2007. All identified risks have been addressed through device design, verification/validation or through documentation (labeling and Instructions for Use) provided to the user.

In summary, performance test (Bench and Simulated Use studies) results support a determination of substantial equivalence to the predicate system. The following Table 6-3 presents the other applicable standards as they pertain to biocompatibility, sterilization and packaging:

Table 6-3: Summary of other applicable standards

Other applicable standards		
Standard ID #	**Title**	**Conclusion**
ISO 14971 (2nd Edition 2007-03-01)	Medical Devices - Application of Risk Management to Medical Devices	Fulfilled
ISO 11135 (2nd Edition 2014-07-15)	Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Passed-Fulfilled (as per Section 015, Sterilization and Shelf Life)
ISO 10993-7 (2nd Edition 2008-10-15)	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	
ISO 11607-2 (1st Edition 2006-04-15)	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes	Passed-Fulfilled (use of pouch previously validated)
ASTM F1886-16 (2016)	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Passed-Fulfilled
ASTM F88-15 (2015)	Standard Test Method for Seal Strength of Flexible Barrier Materials	Passed-Fulfilled
ASTM F2096-11 (2011)	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Passed-Fulfilled
ASTM F1980-16 (2016)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Passed-Fulfilled
ASTM D4169-16 (2016)	Standard Practice for Performance Testing of Shipping Containers and Systems	Passed-Fulfilled
ISO 10993-1 (5th Edition 2018-08)	Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process	Fulfilled (as per Section 016, Biocompatibility)

Biocompatibility: The patient-contacting (direct/indirect fluid path) components of the SAM IO™ Intraosseous Access System, namely the SAM IO™ Needle Set Assembly and the SAM IO™ Extension Tubing Assembly, fulfil the requirements as set forth in:

- *ISO 10993: Biological evaluation of medical devices – Part 1: Guidance on selection of tests.*

Sterilization: The sterile component of the system (the SAM IO™ Needle Set & Accessories) is sterilized via ethylene oxide (EO) sterilization. The sterility to a Sterility Assurance Level (SAL) of 10^{-6} is assured using an EO sterilization method validated in accordance with:

- ANSI/AAMI/ISO 11135:2014, *Sterilization of healthcare products – Ethylene oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*

- AAMI/ANSI/ISO 10993-7:2008(R)2012, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*

Packaging: The sterilization validation, stability (accelerated aging followed by seal integrity and seal strength testing) testing and package (sealing process) validation results demonstrate that the proposed terminally sterilized packaging system allows sterilization, provides physical protection, maintains sterility up to the point of use and allows aseptic presentation of the SAM IO™ Needle Set & Accessories.

CLINICAL TESTING

Clinical testing was not included as part of this submission.

CONCLUSION OF COMPARISON

Based on the performance testing conducted and provided in this submission, it was concluded that the SAM IO™ Intraosseous Access System is substantially equivalent to the EZ-IO® Intraosseous Infusion System (K141117).