July 2, 2024

ZIEN Medical Technologies, Inc.
Tim Nieman
CEO
2490 South 300 West
Salt Lake City, Utah 84115

Re: K240915
Trade/Device Name: ZIEN IO Intraosseous Access System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 28, 2024
Received: April 3, 2024

Dear Tim Nieman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809 ; medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Gang Peng -S

Shruti Mistry
Assistant Director
Division of Drug Delivery and General Hospital Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240915

Device Name
ZIEN IO Intraosseous Access System

Indications for Use *(Describe)*
The ZIEN 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

GENERAL INFORMATION

Submitted by:

Owner's Name: ZIEN Medical Technologies, Inc.
Address: 2490 South 300 West
Salt Lake City, UT 84115 USA

Contact Person: Tim Nieman
Title: CEO
Tel: +1 (385) 444-2666
Email: Tim.nieman@zienmedical.com

Date Prepared:	July 2, 2024
Trade Name:	ZIEN 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:	SAM IO™ Intraosseous Access System, SAM® Medical Products, Inc. (K191488)

DEVICE DESCRIPTION:

The ZIEN IO Intraosseous Access System consists of a single use disposable intraosseous (IO) needle assembly (the ZIEN IO Needle Set) that connects to a reusable manually powered drill (the ZIEN 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).

INDICATION FOR USE:

The ZIEN 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.

INTENDED USE:
For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases.

LABELING AND TECHNOLOGICAL CHARACTERISTICS COMPARISON:

As shown in Table 6-1 (see next page), the proposed ZIEN IO Intraosseous Access System has **identical** intended use and **different** technology characteristics to the currently marketed SAM IO™ Intraosseous Access System (K191488).

Table 6-1: Comparison table

		Proposed system	Predicate system
Device Proprietary Name		ZIEN IO Intraosseous Access System	SAM IO™ Intraosseous Access System
Manufacturer		ZIEN Medical Technologies, Inc.	SAM® Medical Products, Inc.
510(k)		-	K191488
1. LABELING			
Class.	**Regulation**	21 CFR 880.5570	Same
	Product Code	FMI	Same
	Class. Name	Needle, Hypodermic, Single Lumen	Same
Indication for Use:		The ZIEN 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 SAM 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.
Intended Use	**Intended Use:**	For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases.	For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases.
	Rx or OTC	Rx	Rx
	Target population	Adult and pediatric patients who are in need of vascular access.	Same
Contraindications		Fracture in targeted bone Previous, significant orthopedic procedure at site selected for insertion Intraosseous catheter placement in targeted bone within past 48 hours. Infection at site selected for insertion Excessive tissue or absence of anatomic landmarks	Same

	Proposed system	Predicate system
	Not for sternal use	
Labels	Different labels for each needle size. Include relevant symbols and warnings. Identify specification for patient's weight.	Same
Instructions for Use (IFU)	Step-by-step procedure to establish IO access, including the same critical tasks. One (1) IFU document for the Needle Set & Accessories and one (1) IFU document for the Driver.	Same
2. TECHNOLOGY		
Use Environment (Where used)	Emergency settings: Pre-hospital, In hospital, Acute care, Military, and other	Same
Anatomical sites used	Four (4) insertion sites • Proximal tibia • Distal tibia • Humeral head (proximal humerus) • Distal femur (pediatric patients only)	Same
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	• ZIEN IO Needle Sets • ZIEN IO Extension Tubing Set • NeedleVISE® 1-port Sharps Block	• SAM IO™ Needle Sets • SAM IO™ Extension Tubing Set • NeedleVISE® 1-port Sharps Block
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	Same
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

	Proposed system	Predicate system
Shelf life	6 months	Different (12 months) The 6 months expiry claimed for the subject device does not introduce any different questions of safety or effectiveness, the shelf life has been evaluated per ASTM F1980-21
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	Same
Dimensions	• Back handle to trigger: 80mm • Top to bottom: 105mm	Same
Design	The ZIEN IO Driver is a reusable manually operated drill connected to a disposable IO needle assembly.	Same
	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
	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	Same
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, silicone. Since the needle set design and function is the same between the proposed and predicate systems, and the performance of the system has not been altered, the difference in materials does not raise different questions of safety and effectiveness	Different Please see comment # 1 Polycarbonate, stainless steel, santoprene, silicone. Adhesive is used in the predicate Needle Set Assembly.

Discussions of differences in technological characteristics.

Comment # 1

The proposed ZIEN IO Needle Set Assembly uses a press-fit for the Argon needle and assembly whereas the predicate SAM IO™ Needle Set Assembly used adhesive for this junction. This difference is minimal and does not raise different questions of safety or effectiveness. Performance verification data confirms that the press fit design of the proposed system meets the same acceptance criteria as the predicate system. Otherwise, the proposed system and predicate system are identical besides the legal manufacturer and trade name.

NON-CLINICAL TESTING

Performance (Bench) Testing: Performance bench testing was conducted to ensure that the ZIEN 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 ZIEN IO Intraosseous Access System.

Table 6-2: Summary of performance standards

Performance Standards		
Standard ID #	**Title**	**Conclusion**
ISO 80369-7: 2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	Fulfilled Changes made to mold to conform to the updated standard
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 A632-19 (2029)	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	

Simulated use: Simulated use results provided by ZIEN Medical Technologies, Inc. support the conclusion that the proposed device is clinically safe for prescription use. Furthermore, ZIEN Medical Technologies, Inc. conducted a risk analysis on the proposed system in accordance with ISO 14971. 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 14971:2019	Medical Devices - Application of Risk Management to Medical Devices	Fulfilled
ISO 11135:2014	Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Passed-Fulfilled
ISO 10993-7:2008/Amd 2019	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	
ISO 11607-2: 2019	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes	Passed-Fulfilled
ASTM F1886-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Passed-Fulfilled

ASTM F88/F88-23	Standard Test Method for Seal Strength of Flexible Barrier Materials	Passed-Fulfilled
ASTM F2096-11:2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Passed-Fulfilled
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Passed-Fulfilled
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	Passed-Fulfilled
ISO 10993-1:2018	Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process	Fulfilled

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

- *ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Guidance on selection of tests.*

Sterilization: The sterile component of the system (the ZIEN 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 / Amd.1:2019, *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals – Amd.1, applicability of allowable limits for neonates and infants*

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 ZIEN 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 ZIEN IO Intraosseous Access System is substantially equivalent to the SAM IO™ Intraosseous Access System (K191488).