July 28, 2021
Einstein Works LLC
Roy Bachrach
Managing Director
5312 Elm St
Houston, Texas 77081

Re: K211395
Trade/Device Name: NIO-I
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, MHC
Dated: April 28, 2021
Received: May 5, 2021

Dear Roy Bachrach:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211395

Device Name
NIO-I

Indications for Use *(Describe)*
The NIO-I is an intraosseous device intended to provide vascular access in the proximal tibia of infants as an alternative to emergency IV access. It is indicated for use in infants between gestational age of 36 weeks and weight of at least 5 pounds (2.3 Kg) and up to 3 years of age.

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 FOR EINSTEIN WORKS' NIO-I

K211395

1. **Submitter Information**

Einstein Works LLC.
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Houston, TX 77081
Phone: 001-713-7236000
E mail: roy@ps-med.com

Contact person name: Mr. Roy Bachrach - Managing Director
Phone: 001-713-7236000
Email: roy@ps-med.com

2. **Date of Preparation**

July 28, 2021

3. **Identification of Predicate**

Waismed LTD's NIO-I, *Intraosseous infusion device*
cleared under 510(k) number **K190538** on July 10, 2019.

4. **Identification of Subject Device**

a. Regulatory Information

Regulation Name: Needle, Interosseous
Regulation Number: 880.5570
Product Code: Primary: FMI
Secondary: MHC
Common Name: Intraosseous infusion device
Proprietary/Trade name: NIO-I

Einstein Works, LLC.
info@einsteinworksllc.com
www.einsteinworksllc.com

5. Device Description

The NIO-I is a manual intraosseous device. It includes a lightweight ergonomic handle for easy and fast manual insertion of the needle into the medullary cavity. The device is designed specifically for infants between 36 weeks and weight of at least 5 pounds (2.3 Kg) and up to 3 years of age. The NIO-I provides haptic feedback via the stepped-needle design that helps preventing over-penetration into the distal cortex. After insertion of the needle, the user disconnects the handle and pulls out the trocar leaving the cannula inside the medullary cavity. Through the cannula, the caregiver can infuse fluids and drugs that will reach the vascular system.

6. Indications for Use Statement

Characteristics	**Subject Device** Einstein Works LLC NIO-I	**Predicate Device** Waismed Ltd NIO-I K190538
Indications for Use	The NIO-I is an intraosseous device intended to provide vascular access in the proximal tibia of infants as an alternative to emergency IV access. It is indicated for use in infants between gestational age of 36 weeks and weight of at least 5 pounds (2.3 Kg) and up to 3 years of age.	The NIO-I is a intraosseous device intended to provide vascular access in the proximal tibia of infants as an alternative to emergency IV access. It is indicated for use in infants between gestational age of 36 weeks and weight of at least 5 pounds (2.3 Kg) and up to 3 years of age.
Prescription Only or Over the counter	Prescription	Prescription

Discussion of Substantial Equivalence of in Indications for Use statement:
Both devices have the exact same intended use, indications and clinical purpose.

Therefore, in terms of indications for use statement, the NIO-I is substantially equivalent to the selected predicate device.

7. Summary of Technological Characteristics

Table 1: Technological Comparison with the Predicates

Item	Subject Device Einstein Works LLC NIO-I	Predicate Device Waismed Ltd NIO-I K190538	Comment
Target Population	Emergency Care for infant patients (birth to 29 days with minimal limit of gestational age of 36 weeks and weight of 5lb [2.3Kg]).	Emergency Care for infant patients (birth to 29 days with minimal limit of gestational age of 36 weeks and weight of 5lb [2.3Kg]).	Equivalent
Anatomical Sites	Proximal Tibia.	Proximal Tibia.	Equivalent
Environment Used	Hospital, Clinic, Emergency Care.	Hospital, Clinic, Emergency Care.	Equivalent
Design	Consists of: handle, needle gripper, needle housing, trocar needle (trocar + cannula) and needle cover, allowing intraosseous access for the delivery of drugs and fluids.	Consists of: handle, needle gripper, needle housing, trocar needle (trocar + cannula) and needle cover, allowing intraosseous access for the delivery of drugs and fluids.	Equivalent
Mechanism of Action	Manually in three stages: **(1)** The NIO-I needle is manually inserted through the cortex of the bone until change is resistance is felt, indicating the needle penetrated the bone marrow cavity. **(2)** The insertion handle is then disconnected from the needle and, **(3)** the trocar is removed by pulling it upwards.	Manually in three stages: **(1)** The NIO-I needle is manually inserted through the cortex of the bone until change is resistance is felt, indicating the needle penetrated the bone marrow cavity. **(2)** The insertion handle is then disconnected from the needle and, **(3)** the trocar is removed by pulling it upwards.	Equivalent
Over-Penetration	Stepped-needle Exists to provide sensory feedback	Stepped-needle Exists to provide sensory feedback	Equivalent

Item	Subject Device Einstein Works LLC NIO-I	Predicate Device Waismed Ltd NIO-I K190538	Comment
Safety Mechanisms	upon cortex penetration to prevent over-penetration.	upon cortex penetration to prevent over-penetration.	
Insertion Site	In proximal tibia	In proximal tibia	Equivalent
Insertion Site Identification	Extending the patient's leg at the tibia site, the insertion site is located approximately 1cm medial to the tibial tuberosity, or just below the patella (approximately 1cm or one finger width) and slightly medial (approximately 1cm or one finger width), along the flat aspect of the tibia. Then insertion takes place.	Extending the patient's leg at the tibia site, the insertion site is located approximately 1cm medial to the tibial tuberosity, or just below the patella (approximately 1cm or one finger width) and slightly medial (approximately 1cm or one finger width), along the flat aspect of the tibia. Then insertion takes place.	Equivalent
Materials	Needle: Stainless steel 302 (Trocar), stainless steel 316L (Cannula) Plastic components: Polycarbonate Makrolon Rx2530 and ABS PA757 (Handle only, no body contact with the patient).	Needle: Stainless steel 302 (Trocar), stainless steel 316L (Cannula) Plastic components: Polycarbonate Makrolon Rx2530 and ABS PA757 (Handle only, no body contact with the patient).	Equivalent
Biocompatibility	Biocompatible. Complies with ISO 10993-1	Biocompatible. Complies with ISO 10993-1	Equivalent
Needle dwelling time	≤24 Hours	≤24 Hours	Equivalent
Hub Interface	The cannula hub is a standard hub Luer Lock	The cannula hub is a standard hub Luer Lock	Equivalent

Item	Subject Device Einstein Works LLC NIO-I	Predicate Device Waismed Ltd NIO-I K190538	Comment
	appropriate for connecting to any standard infusion system.	appropriate for connecting to any standard infusion system.	
Needle length	15 mm (0.6") with stepped needle for pediatric use.	15 mm (0.6") with stepped needle for pediatric use.	Equivalent
Needle gauge	18G penetration (and 14G above the needle step)	18G penetration (and 14G above the needle step)	Equivalent
Single use	Single use	Single use	Equivalent
Sterilization	Sterile	Sterile	Equivalent
Sterilization method	Gamma irradiation	Gamma irradiation	Equivalent
Sterile Packaging	Sterile barrier	Sterile barrier	Equivalent

Discussion of Substantial Equivalence of in Technological Characteristics:
Both devices have the exact same technological characteristics and principle of operation. Therefore, there are no differences raising any questions of safety and effectiveness.

8. Non-Clinical Performance Testing

Body contact materials were evaluated for biocompatibility in accordance with FDA's Guidance for *Use of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", dated September 04, 2020* and ISO 10993 international standards series as detailed below. Biocompatibility tests included, sensitization, hemolysis, pyrogenicity, cytotoxicity, acute system toxicity and intracutaneous reactivity.

The biocompatibility tests were conducted to verify that the proposed device is not adverse to human tissue based on the following standards:

- ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-4:2017 – Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood.
- ISO 10993-5:2009 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.

Other non-clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. Tests identified under subsections 'a', 'c', 'd', 'e', 'f', 'h' below are based on the company's internal V&V tests' plan, as following described.
Tests identified under subsections 'b', 'g', 'i', 'j', 'k', 'l', 'm' are in compliance with applicable standards as follows:

a) Force required for needle cover removal;
b) Visual inspection for corrosion, per ISO 9626;
c) Force required for needle insertion;
d) Minimal force for insertion of the needle;
e) Force for detachment of the needle housing from the needle gripper;
f) Maximum force for trocar removal after insertion to the platform;
g) Cannula effective length, per ISO 9626 and ISO 7864;
h) Maximum force for cannula removal after insertion;
i) Usability study, per IEC 62366-1;
j) Shelf life, per ISO 11607-1 and ASTM F1980-16;
k) Sterilization validation, per ISO 11137-1, ISO 11137-2, ISO 13004, ANSI AAMI ST72;
l) Limits for acidity or alkalinity, per ISO 7864;
m) Conical fitting, per ISO 594-1 and ISO 594-2.

The test results demonstrated that the proposed device complies with the following standards:

- ISO 594-1:1986 – Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements.
- ISO 594-2:1998 – Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings.

- ISO 11137-1:2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2:2013 – Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose.
- ISO 13004:2013 – Sterilization of health care products – Radiation – Substantiation of selected sterilization dose: Method VDmaxSD.
- ANSI AAMI ST72:2011/(R)2016 – Bacterial endotoxins –Test methods, routine monitoring, and alternatives to batch testing.
- IEC 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices.
- ASTM F1980-16 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ISO 11607-1:2019 – Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 7153-1:1999 – Surgical instruments – Metallic materials – Part 1: Stainless steel.
- ISO 9626:2016 – Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods.
- ISO 7864:2016 – Sterile hypodermic needles for single use – Requirements and test methods.

All tests' results support Einstein Works LLC labeling claims in order to establish substantial equivalency.

9. Clinical Test Conclusion

No clinical Study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

The evaluation of the subject device performance demonstrates that it is as safe and as effective as the legally marketed predicate device.