October 23, 2019
Einstein Works, L.L.C.
% David Makanani
CEO
OMEDtech, L.L.C.
1725 Signal Ridge Drive, Suite 150
Edmond, Oklahoma 73013

Re: K191258
Trade/Device Name: Intraosseous infusion device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: September 13, 2019
Received: September 17, 2019

Dear David Makanani:

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)*
K191258

Device Name
Intraosseous Infusion Device

Indications for Use *(Describe)*

The NIO-P for pediatric is intended to provide Intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients in age 3-12 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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5. 510(k) SUMMARY

The 510(k) Summary is included following this page.

510(K) SUMMARY: K191258

Date	October 16, 2019
SUBMITTER	Linda Taylor, Senior Vice-President Einstein Works, L.L.C. 5312 Elm Street Houston, TX 77081
CONTACT PERSON	Linda Taylor, Senior Vice-President Einstein Works, L.L.C. 5312 Elm Street Houston, TX 77081
DEVICE NAME	
Classification	Class II
Trade Name	Intraosseous Infusion Device
Common Name	Needle, Hypodermic, Single Lumen
Regulation Name	Hypodermic single lumen needle
Classification Regulation	21 C.F.R. 880.5570
Product Code	FMI
PREDICATE DEVICE:	Primary Predicate: WaisMed LTD, NIO- P (Pediatric) Intraosseous Infusion Device (K160805) Secondary Predicate: Einstein Works, L.L.C. NIO- A (Adult) Intraosseous Infusion Device (K182770)

DEVICE DESCRIPTION:

The Einstein Works NIO Pediatric (NIO- P) Intraosseous Infusion Device permits intraosseous access through the Proximal Tibia and the Humeral Head.

The NIO device is comprised of a trocar needle, spring, piston and housing and it resembles a syringe. When activated, a loaded spring is released, and the device injects the needle to a predetermined depth into the bone marrow cavity.

The NIO device also features the same safety latch and trigger mechanism which is found with the predicate device.

Indications for Use:

The NIO- P for Pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients in age 3- 12 years old.

Differences in Indications
There are no differences in indications for use.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Technological Characteristic	**NIO-P Einstein Works, L.L.C.**	**NIO-P Waismed Ltd. (Primary Predicate) (K160805)**	**Comparison**
Sponsor	Einstein Works, LLC	Waismed Ltd	Same device with US company distributing
Indications for Use	The NIO-P for pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients in age 3- 12 years of age.	The NIO-P for pediatrics is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in pediatric patients in age 3- 12 years of age.	Same
Target Population	Emergency Care Patients	Emergency Care Patients	Same
Anatomical Sites	Proximal Tibia	Proximal Tibia	Same
Environment Used	Hospital, Clinic, Emergency Care	Hospital, Clinic, Emergency Care	Same
Design:	Consists of trocar needle, spring, piston and housing.	Consists of trocar needle, spring, piston and housing.	Same

Technological Characteristic	NIO-P Einstein Works, L.L.C.	NIO-P Waismed Ltd. (Primary Predicate) (K160805)	Comparison
Mechanism of Action	The device resembles a syringe and when activated, a loaded spring is released, and the device injects the needle to a predetermined depth into the bone marrow cavity according to the patient age.	The device resembles a syringe and when activated, a loaded spring is released, and the device injects the needle to a predetermined depth into the bone marrow cavity according to the patient age.	Same
Components	- The trocar needle - The spring - The piston - The housing - The needle holder - The safety latch - The trigger - The needle stabilizer with the location arrow	- The trocar needle - The spring - The piston - The housing - The needle holder - The safety latch - The trigger - The needle stabilizer with the location arrow	Same
Dimensions (packaging)	Length 17.5cm Width 8.8cm Depth 4.7cm	Length 17.5cm Width 8.8cm Depth 4.7cm	Same
Weight (in package)	107.6gm (0.24lbf)	107.6gm (0.24lbf)	Same
Safety Mechanisms	1. Rotational safety latch to prevent accidental activation 2. Simultaneous pressing of device against the bone and pulling of trigger mechanism required to activate device.	1. Rotational safety latch to prevent accidental activation 2. Simultaneous pressing of device against the bone and pulling of trigger mechanism required to activate device.	Same
Materials	Stainless steel (trocar needle & cannula) Brass 360 nickel-plated (hub) Makrolon® Rx2530 polycarbonate (Plastic parts with direct contact to skin)	Stainless steel (trocar needle & cannula) Brass 360 nickel-plated (hub) Makrolon® Rx2530 polycarbonate (Plastic parts with direct contact to skin)	Same

Technological Characteristic	NIO-P Einstein Works, L.L.C.	NIO-P Waismed Ltd. (Primary Predicate) (K160805)	Comparison
Hub Interface	The cannula hub is a standard metal hub Luer Lock appropriate for connecting to any standard infusion system.	The cannula hub is a standard metal hub Luer Lock appropriate for connecting to any standard infusion system.	Same
Needle Fixation	Pediatric needle stabilizer	Pediatric needle stabilizer	Same
Labeling	Einstein Works labeling is the same basic labeling as the Waismed but clarity was added for needle penetration and appropriateness of the target population	Same basic labeling as Waismed labeling.	Same basic labeling with clarifications added to the "Instruction for Use".

This 510 (K) submission represents changes in labeling (Sponsor and instructions for use). There are no changes in the materials and design of proposed device, because the proposed device and the predicate device are the same device.

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

No additional performance testing was performed to support the proposed changes because the device is identical. Changes to labeling did not require bench testing to support substantial equivalence.

PERFORMANCE TESTING – CLINICAL

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical testing, the Einstein Works intraosseous infusion device performs safely, as intended, and the comparative discussion of intended use, principle of operation, and technological characteristics, it is determined that the Einstein Works intraosseous infusion device is substantially equivalent to the predicate device, WaisMed NIO Intraosseous infusion device.