DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 23, 2016

WaisMed Ltd.
% Mr. Jonathan Kahan
Partner
Hogan Lovells US, LLP
Columbia Square, 555 Thirteenth St
Washington, DC 20004

Re: K160805
Trade/Device Name: NIO-P
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: April 29, 2016
Received: April 29, 2016

Dear Mr. Kahan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160805

Device Name
NIO-P

Indications for Use *(Describe)*
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 between 3 and 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.

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510(k) SUMMARY K160805

Applicant Name:

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Date Prepared: June 17, 2016

Trade Name: NIO-P
Classification Name: 880.5570 Hypodermic single lumen needle, (Product code FMI)
Classification: Class II
Predicate Devices:

		Manufacturer / Owner	**510(k) No.**
Predicate Device	NIO Adult	WaisMed Ltd.	K142086
Reference Device	B.I.G Bone Injection for Pediatrics	WaisMed Ltd.	K022415

Device Description:

The NIO product family (Adult and Pediatric) is an upgrade in terms of design and structure to the company's B.I.G. Bone Injection Gun product family. The NIO product family has already one cleared model, for the adult population NIO Adult (K142086).

Both product families NIO and BIG are composed of a trocar needle, spring, piston, and housing that contains safety mechanisms to prevent accidental device activation. Both devices are positioned onto the appropriate insertion site.

Both product families have the same principle of operation. The device resembles a syringe and, when activated, a loaded spring is released and the device injects a needle to a predetermined depth into the bone marrow cavity. The user then pulls out the trocar needle, leaving the cannula inside the bone marrow cavity. Through the cannula, fluids and drugs can be delivered to the vascular system via the bone marrow cavity.

The NIO-P device is designed to detect the proper injection point. In addition, the NIO-P is also equipped with a unique, adjustable needle penetration depth according to the age group, as part of the stabilizer. Both features are designed to improve accuracy in detecting the insertion point and needle penetration depth.

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 between 3 and 12 years of age.

Performance Data:

Provided performance data include the following validations and studies:

1) Insertion Point and Penetration Depth Validation.
2) Adequate Spring Force and Bone Integrity Following Activation Validation.
3) Needle Stabilizer Validation.
4) Hub-Cannula/Hub-Needle Bond Strength Testing (According to ISO 7864).
5) Structural Deformation and Needle Integrity Test.

Substantial Equivalence:

The indications of the NIO-P are identical to those of the reference device, the BIG-P (K022415), except that the NIO-P is specifically indicated for pediatric patients between 3 and 12 years of age. The technological characteristics of the modified NIO-P device, as compared to

the predicate NIO-A device (K142086) are identical except for the modification of the needle stabilizer to allow detection of the accurate insertion point and the adjustable needle depth penetration. This modification has been validated by bench testing, and does not raise new types of safety or effectiveness questions. A comparison table between the subject and predicate devices is provided below.

	NIO-A Waismed Ltd. Predicate Device (K142086)	**BIG-P Waismed Ltd. Reference Device (K022415)**	**NIO-P Waismed Ltd. (Modified Device)**
Product Classification	Regulation number: 880.5570 Code: FMI, Class: II	Same	Same
Indications for Use	The NIO is intended to provide intraosseous access in the proximal tibia, as an alternative to IV access during emergencies. The device is for use in adult patients only. The NIO is indicated for use in providing intraosseous access as an alternative to IV access during emergencies. Humeral head IO access is indicated when rapid fluid or pharmacological resuscitation is required and intravenous access is not possible. The device is for use in adult patients only.	The Bone Injection Gun (B.I.G.) 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 up to 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 between 3 and 12 years of age.
Environment Used	Hospital, Clinic, Emergency Care	Same	Same
Design:	Consists of trocar needle, spring, piston and housing.	Same	Same
Dimensions (packaging)	Length 17.5cm Width 8.8cm Depth 4.7cm	Length 16.5cm Width 7.4cm Depth 2.8cm	Length 17.5cm Width 8.8cm Depth 4.7cm
Weight (in package)	113.8gm (0.25lbs)	80gm (0.18lbs)	107.6gm (0.24lbf)

	NIO-A Waismed Ltd. Predicate Device (K142086)	BIG-P Waismed Ltd. Reference Device (K022415)	NIO-P Waismed Ltd. (Modified Device)
Materials	Stainless steel (trocar needle & cannula) Brass 360 nickel-plated (hub) Makrolon® Rx2530 polycarbonate (Plastic parts with direct contact to skin)	Same	Same
Hub Interface	The cannula hub is a standard metal hub Luer Lock appropriate for connecting to any standard infusion system.	Same	Same
Needle length	42.0mm (1.65”)	23.6mm (1.31”)	38.1mm (1.5")
Needle gauge	15G	18G	18G
Sterilization	Single use, sterile	Same	Same
Sterilization method	Gamma sterilization	Same	Same

Conclusions:

Based on the performance testing and comparison to the predicate and reference devices, the modified NIO-P is substantially equivalent to the NIO-A.