July 22, 2021
WaisMed Ltd
Shifra Hoch
QA/RA Manager
10 Amal St. Afek Industrial Park
Rosh Ha'Ayin, 4809234
Israel

Re: K211968
Trade/Device Name: NIO+ Adult
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: June 21, 2021
Received: June 24, 2021

Dear Shifra Hoch:

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)*
K211968

Device Name
NIO+ Adult

Indications for Use *(Describe)*
The NIO+ Adult is intended to provide intraosseous (IO) access in the proximal tibia and the humeral head as an alternative to emergency IV access. Per urgent medical necessity, humeral head IO access may be used when rapid fluid or pharmacological resuscitation is required. The device is intended for use in adult patients only.

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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K211968

Special 510(k) Summary

NIO+ Adult

510(k) Summary:

1. **Submitter Information**

Name: WaisMed Ltd
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Rosh Ha'Ayin, Israel
Contact Person: Shifra Hoch
Phone: +972-9-951-7444
E mail: shifra@persysmedical.com

2. **Date of Preparation**

22 June 2021

3. **Subject Device**

Trade Name: NIO+ Adult
Common Name: Intraosseous infusion device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Product Code: FMI

4. **Predicate Device**

NIO Adult (WaisMed Ltd., K142086).

5. **Device Description**

The NIO+ Adult (NIO+) is intended to be used with the same patient population and same age range. The NIO+ utilizes the very same technology and has the same operation method. The main difference is that the NIO+ provides a more physically robust version of the NIO Adult (NIO-A) which was selected to serve as the primary predicate device for this submission. The NIO+ was designed to better serve in tactical settings, such as battlefields, as the device and its package are more durable. It should be noted that the NIO-A is currently in use for all segments and settings that the NIO+ is targeted for. The additional robustness of the NIO+ is achieved by utilizing raw

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materials that have higher mechanical properties. The sterile single unit packaging robustness was increased, by using a rigid-blister and rigid plastic cover to protect the Tyvek paper. In addition, the maximal storage temperature was increased to 50°C versus room temperature, in order to assure that the device can function such extreme temperatures.

All NIO products are intended to be used by skilled, authorized medics, nurses, paramedics and doctors who are trained to use the device in military, emergency services and hospitals environments. The products are for single use and supplied sterile.

6. Indications for Use Statement

Table 7 – Indications for Use Comparison with the Predicate

Characteristics	**Subject Modified Device** WaisMed NIO+	**Predicate Device** WaisMed NIO-A K142086
Indications for Use	The NIO+ Adult is intended to provide intraosseous (IO) access in the proximal tibia and the humeral head as an alternative to emergency IV access. Per urgent medical necessity, humeral head IO access may be used when rapid fluid or pharmacological resuscitation is required. The device is intended for use in adult patients only.	The NIO Adult 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 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.
Prescription only or Over the counter	Prescription	Prescription

Discussion of Differences in Indications for Use statement:

The NIO+ and the NIO-A have the same intended use, indications and clinical purpose. The only difference between both devices is the shelf life and storage conditions which are more suitable for military situations in extreme conditions.

Therefore, in terms of indications for use statement, the NIO+ is substantially equivalent to the selected predicate devices.

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7. Summary of Technological Characteristics

Table 8 – Technological Comparison with the Predicate

Item	**Subject Modified Device** WaisMed NIO+	**Predicate Device** WaisMed NIO-A K142086	Comment
Target Population	Adults	Adults	Equivalent
Anatomical Sites	Proximal tibia and humeral head	Proximal tibia and humeral head	Equivalent
Environment Used	Hospital, clinic, emergency care. Additionally, may be used under extreme temperature conditions (50°c).	Hospital, clinic, emergency care, stored and used in room temperature.	Equivalent
Design	Automatic single-use device, including a pre-loaded spring that releases the needle to a predetermined IO depth.	Automatic single-use device, including a pre-loaded spring that releases the needle to a predetermined IO depth.	Equivalent
Mechanism of Action	The device resembles a syringe and when activated, a loaded spring is released and the device injects the needle to a penetration depth of 25±3mm into the bone marrow cavity.	The device resembles a syringe and when activated, a loaded spring is released and the device injects the needle to a penetration depth of 25±3mm into the bone marrow cavity.	Equivalent
Safety Mechanisms	1. Rotational cap to prevent accidental activation; 2. Simultaneous pressing of device against the bone and pulling of the trigger mechanism required to activate the device.	1. Rotational cap to prevent accidental activation; 2. Simultaneous pressing of device against the bone and	Equivalent

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Item	**Subject Modified Device** WaisMed NIO+	**Predicate Device** WaisMed NIO-A K142086	Comment
		pulling of the trigger mechanism required to activate the device.	
Insertion depth	Proximal tibia/humeral head: 2.5(cm)	Proximal tibia/humeral head: 2.5(cm)	Equivalent
Insertion Site Identification	Proximal tibia: Approximately 1 inch or 2 cm medially and 1/2 inch or 1 cm proximally to the Tibial tuberosity. Humeral head: greater tubercle next to the head of the humerus.	Proximal tibia: Approximately 1 inch or 2 cm medially and 1/2 inch or 1 cm proximally to the Tibial tuberosity. Humeral head: greater tubercle next to the head of the humerus.	Equivalent
Materials	1. Stainless steel (trocar and cannula needle) 2. Brass nickel-plated 3. Plastic parts: Polycarbonate 4. Body: Ultem 5. Spring: Stainless Steel	1. Stainless steel (trocar and cannula needle) 2. Brass nickel-plated 3. Plastic parts not including Body: Polycarbonate 4. Body: Polycarbonat 5. Spring: Music wire	Difference in materials. This change does not lead to new questions of safety and effectiveness.
Biocompatibility	Biocompatible. Complies with ISO 10993-1	Biocompatible. Complies with ISO 10993-1	Equivalent

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Item	**Subject Modified Device** WaisMed NIO+	**Predicate Device** WaisMed NIO-A K142086	Comment
Needle dwelling time	≤24 Hours	≤24 Hours	Equivalent
Hub Interface	The cannula hub is a standard hub Luerappropriate for connecting to any standard infusion system.	The cannula hub is a standard hub Luer appropriate for connecting to any standard infusion system.	Equivalent
Needle length	42mm	42mm	Equivalent
Needle gauge	15G	15G	Equivalent
Single use	Single use	Single use	Equivalent
Sterilization	Sterile	Sterile	Equivalent
Sterilization method	Gamma irradiation	Gamma irradiation	Equivalent
Sterile Packaging	PETG injected sealed with Tyvek	PET-A sealed with Tyvek	Difference in materials. This change does not lead to new questions of safety and effectiveness.
Storage Conditions	5 years at room temperature 5 years at 50°C	5 years at room temperature	Difference in storage conditions. This change does not lead to new questions of safety and effectiveness.

Discussion of Technological Characteristics

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

The change in raw materials of the non-contacting components (body and spring) and of the packaging, contributes to the robustness of the NIO+ device in comparison to the NIO-A, which enables its use under tactical settings, especially for extreme conditions and temperatures, as supported by the additional storage conditions of 5 years at 50°C. These differences were assessed by performance testing, and there were no new questions of safety or effectiveness.

8. **Non-Clinical Performance Testing**

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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 June 16, 2016* and ISO 10993 international standards series as detailed below.
The NIO-A and NIO+ are being manufactured using the same needles and the same raw materials for body contacting components. Therefore, no additional tests were necessary to evaluate the safety of the NIO+. Biocompatibility tests that were performed for the NIO-A, and apply for the NIO+ included, sensitization, hemolysis, pyrogenicity, cytotoxicity, acute system toxicity and intracutaneous reactivity.

The biocompatibility tests were conducted to verify that the proposed device will not adversely affect 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 10993-11:2006 – 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 predicates. The tests are as follows. Tests identified under subsections 'a', 'b', 'c' below are based on WaisMed V&V tests plan.

Tests identified under subsections 'd', 'e', 'f', 'g', 'h' are in compliance with applicable standards as follows:

a) Reliability testing of trigger mechanism and penetration depth;

b) Compressed spring force;

c) Trigger safety mechanisms;

d) Cannula effective length, per ISO 9626 and ISO 7864;

e) Environmental and transportation testing, per ASTM D4332-14 and ASTM D4169;

f) Shelf life, per ISO 11607-1 and ASTM F1980-16;

g) Sterilization validation, per ISO 11137-1, ISO 11137-2, ISO 13004, ANSI AAMI ST72;

h) 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 VD_{max} SD.
- ANSI AAMI ST72:2011/(R)2016 – Bacterial endotoxins –Test methods, routine monitoring, and alternatives to batch testing.
- ASTM F1980-16 – Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM D4332-14 – Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-16 – Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 11607-1:2016 – 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 WaisMed's 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 devices.