510(K) SUMMARY: K182770

Date	April 9, 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 Tel: (888) 737-7978
DEVICE NAME	
Classification	Class II
Trade Name	Adult Intraosseous Infusion Device
Classification Regulation	21 C.F.R. 880.5570 (Hypodermic single lumen needle)
Product Code	FMI
Review Panel	General Hospital
PREDICATE DEVICE:	WaisMed LTD NIO- A Intraosseous Infusion Device (K142086)
INTENDED 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.

DEVICE DESCRIPTION:

The Adult NIO 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 device design is the same as the predicate and no changes have been made.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

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

Technological Characteristic	**NIO Device Waismed Ltd. (K142086)**	**NIO Device Einstein Works, L.L.C.**
Product Code, Class	FMI, Class II	FMI, Class II
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 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.
Target Population	Emergency Care Patients	Emergency Care Patients
Anatomical Sites	Proximal Tibia and Humeral Head	Proximal Tibia and Humeral Head
Environment Used	Hospital, Clinic, Emergency Care	Hospital, Clinic, Emergency Care
Energy Used / Delivered	No energy delivered	No energy delivered
Design:	The NIO consists of trocar needle, spring, piston and housing.	The NIO consists of trocar needle, spring, piston and housing.
- 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 ± 3 mm 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 ± 3 mm into the bone marrow cavity.

Technological Characteristic	NIO Device Waismed Ltd. (K142086)	NIO Device Einstein Works, L.L.C.
- Components	The NIO device consists of the following components: - The trocar needle - The spring - The piston - The housing - The needle holder - The safety latch - The trigger - The needle stabilizer	The NIO device consists of the following components: - The trocar needle - The spring - The piston - The housing - The needle holder - The safety latch - The trigger The needle stabilizer
- Dimensions (packaging)	Length 17.3cm Width 8.8cm Depth 4.7cm	Length 17.3cm Width 8.8cm Depth 4.7cm
- Weight (in package)	110gm (0.24lbs)	110gm (0.24lbs)
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.
Standards Met	- ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment; - ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices ISO 7864, Sterile hypodermic needles for single use	- ISO 594, Conical Fittings with a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment; - ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices ISO 7864, Sterile hypodermic needles for single use
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)
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.
Needle Fixation	Needle stabilizer	Needle stabilizer

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

- Performance data were not required to determine substantial equivalence.

PERFORMANCE TESTING – CLINICAL

There are no clinical data submitted with this Notification.

CONCLUSION:

The Einstein Works NIO Adult intraosseous infusion device is the same as the WaisMed NIO Intraosseous infusion device. It has the same intended use and the same technological characteristics. It is substantially equivalent.