DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 26, 2016

Cook Incorporated
Ms. Julia Ferguson
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K160887
Trade/Device Name: Cook Intraosseous Infusion Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 27, 2016
Received: June 28, 2016

Dear Ms. Ferguson:

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,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting 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)*
K160887

Device Name
Cook Intraosseous Infusion Needles

Indications for Use *(Describe)*
Cook Intraosseous Infusion Needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.

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 -K160887

Intraosseous Infusion Needles

21 CFR §880.5570

Date Prepared: 27 June 2016

Submitted By:
Applicant: Cook Incorporated
Contact: Steven Lawrie
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact Phone Number: (812) 335-3575 x104518
Contact Fax Number: (812) 332-0281

Device Information:
Trade Name: Cook Intraosseous Infusion Needles
Common Name: Intraosseous Infusion Needles
Classification Name: Needle, Hypodermic, Single Lumen
Regulation: 21 CFR §880.5570
Product Code FMI - Needle, Hypodermic, Single Lumen

Predicate Device:

- K913258 - Disposable Intraosseous Infusion Needles

Device Description:

The Intraosseous Infusion Needles consist of a two-part assembly with a needle and a cannula. The device is pre-assembled with the hub of the cannula attached to the needle by a luer-lock connection. The cannula shaft is made of stainless steel and is available in 14, 16, or 18 Gauge, with shaft lengths of 2.5, 3.0, or 4.0 cm. The hub and base plate of the cannula are constructed of either nickel-plated brass or polycarbonate. The stylet of the needle is constructed of stainless steel. For placement, the needle assembly is inserted into the bone with firm, downward pressure using a clockwise rotation, with the needle tip directed away from the joint space and epiphyseal plate; the needle orientation should always be maintained in line with the long axis of the bone. The stylet of the needle can then be removed by stabilizing the base plate of the cannula and turning the knob of the needle counterclockwise to disengage the needle from the cannula. Once access to the intramedullary space is confirmed, infusion of drugs and fluids can be initiated through the cannula. Five different versions of Cook Intraosseous Infusion Needles, with the same basic design, will be made available:

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- Dieckmann Intraosseous Infusion Needle – High Density Hub/Brass Design
- Dieckmann Intraosseous Infusion Needle – Standard Hub/Polycarbonate Design
- Intraosseous Infusion Needles – Standard Tip Design
- Intraosseous Infusion Needle with Adjustable Flange
- Sussmane-Raszynski Intraosseous Infusion Needle

Intended Use:

Intraosseous infusion needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.

Comparison to Predicates:

The Intraosseous Infusion Needles are substantially equivalent to the predicate device, the Disposable Intraosseous Infusion Needles (K913258) in that these devices have similar designs, methods of construction and operation, and indications for use. The differences from the predicate include material changes (i.e., the hub and base plate material have been modified to be either nickel-plated brass or polycarbonate and the stylet luer-lock material has been modified to be either nickel-plated brass or polypropylene) and the addition of a device variant (i.e., the Intraosseous Infusion Needle with Adjustable Flange). A detailed comparison to the predicate is provided in Table 1.

Table 1: Substantial equivalence comparison

		Predicate Device	**Subject Device**
		Disposable Intraosseous Infusion Needles (K913258)	**Intraosseous Infusion Needles**
Regulation		880.5570	880.5570
Product Code		FMI	FMI
Classification		II	II
Intended Use	**From Device Description in 510(k) (K913258)**	Intraosseous infusion needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.	Intraosseous infusion needles are sterile, disposable devices used primarily during pediatric emergencies as an alternative to unsuccessful intravenous access to allow for effective infusion of resuscitative drugs or fluids.
Cannula	**Hub Material**	Brass	Nickel Plated Brass or Polycarbonate
	Base Plate Material	Stainless Steel	Nickel Plated Brass or Polycarbonate
	Solder Material	All State 430	Identical

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Table 1: Substantial equivalence comparison (continued)

		Predicate Device	Subject Device
		Disposable Intraosseous Infusion Needles (K913258)	**Intraosseous Infusion Needles**
Cannula	**Weld Material**	Silweld 1618	Identical
	Cannula Shaft Material	Stainless Steel	Identical
	Cannula Shaft Diameter (gauge)	12, 14, 15.5, 16, 18	14, 15.5, 16, 18
	Cannula Shaft Length (cm)	1.8, 2.3, 2.5, 3.0, 4.0	2.5, 3.0, 4.0
Needle	**Knob Material**	Nylon 6 (Black)	Nylon 6 (Grey)
	Stylet Luer-lock Material	Brass	Nickel Plated Brass or Polypropylene
	Adhesive Material	Thermoset DC140	RenCast 140
	Solder Material	Allstate #430	Identical
	Beveled Stylet Material	Stainless Steel	Identical
	Stylet Length (cm)	1.8, 2.3, 5.1, 5.5, 5.6, 6.1, 6.6	4.2, 4.6, 4.65, 4.7, 5.51, 5.6, 5.65, 5.7, 6.8, 7.0
Packaging		PETG Tray/Tyvek	Identical
Sterilization		EtO	Identical
SAL		10^{-6}	Identical

Technological Characteristics:

Modifications to the subject Intraosseous Infusion Needles were evaluated per ISO 14971. The following tests have been conducted to ensure reliable design and performance under the specified design requirements based on these modifications:

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Table 2: Design Control Activities

Modification	Risk Addressed	Design Control Activity
Modification to hub and base plate material	Modified device is not biocompatible	Biocompatibility was evaluated per ISO 10993-1. Testing included cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity (acute), hemolysis, and rabbit pyrogen testing.
	Failure of hub to shaft bond	Tensile Strength testing was performed per BS EN ISO 11070.
		Liquid Leakage testing was performed per BS EN ISO 10555
Modification to stylet luer-lock material	Failure of knob to stylet bond	Tensile Strength testing was performed per BS EN ISO 11070.
		Unscrewing Torque testing was performed per ISO 594-2
	Overriding of luer lock during torqueing	Resistance to Overriding testing was performed per ISO 594-2

The results of all tests met their predetermined acceptance criteria.

Conclusion:

The results of performance tests support a conclusion that the proposed Intraosseous Infusion Needles have met the design input requirements based on the intended use and support the conclusion that these devices perform in a substantial equivalent manner as compared to the predicate.