June 7, 2018

Cook Incorporated
Johnathan Liu
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K173155
Trade/Device Name: Pakter Curved Needle Set
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 7, 2018
Received: May 8, 2018

Dear Johnathan Liu:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173155

Device Name
Pakter Curved Needle Set

Indications for Use *(Describe)*
The Pakter Curved Needle Set is intended for discography, diagnostic sampling, aspiration, and injection.

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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2.0 510(k) SUMMARY

Pakter Curved Needle Set
21 CFR §807.92(c)
Date Prepared: May 2, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
510(k) Number:	K173155
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Johnathan Liu
Email:	regsubmissions@cookmedical.com
Contact Phone Number:	(812) 335-3575 x104509
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Pakter Curved Needle Set**
Common Name:	Needle, Conduction, Anesthetic (W/Wo Introducer)
Classification Name:	Anesthesia conduction needle
Regulation:	21 CFR §868.5150
Product Code:	BSP
Device Class:	II
Classification Panel:	Anesthesiology

Predicate Device:

The Pakter Curved Needle Set is considered substantially equivalent to the following device: Atraumatic Standard Sprotte® Needle (K911260, Pajunk GMBH) cleared on October 21, 1991.

Device Description:

The Pakter Curved Needle Set is manufactured as a coaxial needle set and includes a pre-shaped curved needle and an introducer needle. The curved needle consists of a nitinol cannula connected to a polycarbonate hub at the proximal end and is characterized with a distal curve and a 30° bevel distal tip. It also includes a stainless steel stylet that is designed for a transitional fit. The curved needle with stylet is 25 gage in diameter and has a length of 20 or 15 centimeters. The introducer needle consists of a stainless steel cannula connected to an acrylic hub at the proximal end. The introducer needle is also designed with a stainless steel stylet. The introducer needle with stylet is 21 gage in diameter and has a length of 15 or 10 centimeters. When used as intended, the introducer needle and stylet are first inserted percutaneously and advanced adjacent to the target anatomy. After removing the introducer needle stylet, the curved needle is then inserted through the introducer needle cannula and slowly advanced to the target anatomy. The Pakter Curved Needle Set is sterilized by ethylene oxide and intended for one-time use.

Indications for Use:

The Pakter Curved Needle Set is intended for discography, diagnostic sampling, aspiration, and injection.

Comparison to Predicate Device:

The Pakter Curved Needle Set and the predicate device, Atraumatic Standard Sprotte® Needle (K911260), are considered substantially equivalent in that these devices are identical in principles of operation and fundamental technologies. Additionally, the subject device has similar indications for use, coaxial design, materials, and dimensions as the predicate device.

The differences in technological characteristics between the subject device and the predicate device include the following:

- Materials – The subject device needle cannula is made of Nitinol, while the predicate device's cannula is made of stainless steel. The subject device's introducer needle cannula hub is acrylic, while the predicate device's hub is made of polycarbonate.
- Dimensions – The subject device's needle cannula and introducer needle cannula are longer in length than those of the predicate device; the subject device's needle cannula gage size is smaller than that of the predicate device; the needle cannula tip of the subject device is curved with a 30-degree bevel, while that of the predicate

device is straight with a pencil point bevel; and the introducer needle cannula gage size of the subject device is smaller than that of the predicate device.

- Additionally, the subject device set includes a needle cannula stylet, while the predicate device set does not.

These differences in technological characteristics between the subject and predicate devices do not raise any different questions of safety and/or effectiveness.

		PREDICATE DEVICE	SUBJECT DEVICE
		Atraumatic Standard Sprotte® Needle (K911260)	**Pakter Curved Needle Set**
Regulation		21 CFR § 868.5150	Identical
Product Code		BSP	Identical
Classification		II	Identical
Indications for Use		To gain entry into or puncture the spinal cavity permitting injection/withdrawal of fluids for purposes of diagnostic lumbar puncture, myelography/discography and chemonuceolysis procedures.	The Pakter Curved Needle Set is intended for discography, diagnostic sampling, aspiration, and injection.
Device is for One-time Use		Yes	Identical
Needle*	**Cannula Material**	Stainless Steel	Nitinol
	Cannula Hub Material	Polycarbonate	Identical
	Cannula Length	7 to 15 cm	15, 20 cm
	Cannula Size	19.5 to 24 gage	25 gage
	Cannula Tip	Straight, Pencil point	Curved, 30° bevel
	Stylet Material	Stainless Steel	Identical
Introducer Needle	**Cannula Material**	Stainless Steel	Identical
	Cannula Hub Material	Polycarbonate	Acrylic
	Cannula Size	0.7 to 1.0 mm	21 gage (0.82 mm)
	Cannula Length	3, 4 cm	10, 15 cm
	Stylet Material	No stylet	Stainless Steel
Packaging		Pouch	Peel Pouch
Sterilization Method		EtO	Identical
Sterility Assurance Level		10^{-6}	Identical

*Subject device needle is curved. Predicate device needle is not curved.

Indications for Use: The indications for use of the subject device is similar to that of the predicate device. Both the subject device and predicate device are indicated for discography. Although the wording is different, the subject device indications for

"diagnostic sampling, aspiration, and injection" are synonymous with the predicate device indications for "injection/withdrawal of fluids." The only difference between the subject device and predicate device intended use statements is that the subject device is not indicated for myelography and chemonucleolysis. The wording differences and exclusion of myelography and chemonucleolysis in the indications for use statement of the subject device do not raise different questions of safety and/or effectiveness.

Technological Characteristics:

The subject device, Pakter Curved Needle Set, underwent the following applicable testing to ensure reliable design and performance under the specified testing parameters:

<u>Bench Testing (including time-zero and five-year accelerated aged testing)</u>

- Tensile Strength
  - Curved Needle Cannula Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the curved needle cannula shall be greater than or equal to 22 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Curved Needle Stylet Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the curved needle stylet shall be greater than or equal to 11 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Introducer Needle Cannula Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the introducer needle cannula shall be greater than or equal to 44 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Introducer Needle Stylet Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the introducer needle stylet shall be greater than or equal to 22 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
- Stiffness – Introducer Needle Cannula and Stylet: The introducer needle cannula and stylet shall show a deflection of less than 0.45 mm when a force of 9.6 N is applied in accordance with BS EN ISO 9626:2016. The acceptance criterion was met.

- Resistance to Breakage
  - Curved Needle Cannula – The curved needle cannula shall show no visible breakage after cyclic testing in accordance with BS EN ISO 9626:2016. The acceptance criterion was met.
  - Introducer Needle Cannula – The introducer needle cannula shall show no visible breakage after cyclic testing in accordance with BS EN ISO 9626:2016. The acceptance criterion was met.
- Resistance to Corrosion – Following testing in accordance with the method given in Annex B of BS EN ISO 11070, the curved needle and introducer needle will be examined for visual signs of corrosion and the results will be reported. The acceptance criterion was met.
- Tensile Strength Post-Corrosion
  - Curved Needle Cannula Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the curved needle cannula shall be greater than or equal to 22 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Curved Needle Stylet Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the curved needle stylet shall be greater than or equal to 11 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Introducer Needle Cannula Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the introducer needle cannula shall be greater than or equal to 44 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
  - Introducer Needle Stylet Hub-to-Shaft – The peak tensile load for the hub-to-shaft section of the introducer needle stylet shall be greater than or equal to 22 N in accordance with BS EN ISO 7864:2016 and BS EN ISO 11070:2014. The acceptance criterion was met.
- Liquid Leakage Under Positive Pressure – The curved needle cannula shall maintain a positive pressure of 300 kPa for 30 seconds without leakage in accordance with BS EN ISO 11070:2014. The acceptance criterion was met.
- Patency of Lumen – A stainless steel stylet with a diameter of 0.009 inches (0.23 mm) shall pass through the lumen of the curved needle cannula. The acceptance criterion was met.

- Dimensional Analysis and Compatibility – Testing conducted demonstrated that the curved needle and introducer needle dimensions are within the specified tolerances and the components are compatible.

Biocompatibility Testing:

- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, material mediated pyrogen, and hemolysis study demonstrated the biocompatibility of the subject device.

Conclusion:

The results of these tests confirm that the Pakter Curved Needle Set meets the design input requirements based on the intended use and support the conclusion that this device does not raise different questions of safety and/or effectiveness and is substantially equivalent to the predicate device, Atraumatic Standard Sprotte® Needle (K911260).