September 26, 2021

DiscCath LLC
Gregory Lutz
Chief Executive Officer
62 E 88th Street
New York, New York 10128

Re: K212328
Trade/Device Name: DiscCath Needle Set
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: July 23, 2021
Received: July 27, 2021

Dear Gregory Lutz:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K212328

Device Name
DiscCath Needle Set

Indications for Use *(Describe)*
The DiscCath Needle Set is intended to provide access into the intervertebral disc for discography and injection of fluids.

The device is intended for adult patients.

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

K212328

Submission Type: Traditional 510(k)

Submitter Information:

DiscCath LLC.
62 E 88th Street
New York, NY 10128

Contact Person:

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Date Prepared:

July 19, 2021

Subject Device Information:

Proprietary Name:	DiscCath Needle Set
Common Name:	Needle, Conduction, Anesthetic (W/Wo Introducer)
Classification Name:	Anesthesia Conduction Needle
Regulation:	21 CFR 868.5150
Product Code:	BSP
Device Classification:	Class II
Classification Panel:	Anesthesiology

Predicate Devices:

Proprietary Name:	Pakter Curved Needle Set (Primary)
Manufacturer:	Cook Incorporated
510(k) Number:	K173155
Common Name:	Needle, Conduction, Anesthetic (W/Wo Introducer)
Classification Name:	Anesthesia Conduction Needle
Regulation:	21 CFR 868.5150
Product Code:	BSP
Device Classification:	Class II
Classification Panel:	Anesthesiology

The selected primary predicate is appropriate based on similarity in indications for use, principle of operation as well as materials and other technological characteristics between it and the DiscCath Needle Set. Where differences exist between the subject and predicate device, the differences are bridged using the following reference predicates:

Device	Reference Devices	
	IMD Lumbar Puncture Needle (Reference Predicate)	**SPINECATH Intradiscal Catheter (Reference Predicate)**
Manufacturer	International Medical Development, Inc.	Oratec Interventions, Inc.
510(k) Reference/Clearance Date	K170112 / February 2, 2018	K993967 / December 17, 1999
Regulation	21 CFR 868.5150	21 CFR 878.4400
Product Code	BSP	GEI
Classification	II	II
Reason for Reference	Spinal needle with closed-end tip with side holes indicated for discography procedures	Intradiscal catheter provided with 17 gauge introducer.

Device Description:

The DiscCath Needle Set is a single-use intradiscal injection needle comprised of a 17 gauge x 6" Introducer Needle and a 21 gauge x 10.2 inch (nominal) Injection Catheter. The Introducer Needle is comprised of a stainless-steel cannula and metal hub with a stainless-steel stylet with metal hub. The Introducer Needle has a cannula and stylet match ground bevel point at the distal tip which allows for penetration into the intervertebral disc.

The Injection Catheter is comprised of a nitinol shape-set tube and a molded plastic hub. The injection catheter tubing is flexible with a curved tip welded closed at the distal end and includes a laser cut side-hole that allows for the injection of a fluid.

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 catheter is then inserted through the Introducer Needle cannula and slowly advanced to the target anatomy.

The DiscCath Needle Set is sterilized by ethylene oxide and intended for single use.

Indications for Use:

The DiscCath Needle Set is intended to provide access into the intervertebral disc for discography and injection of fluids. The device is intended for adult patients.

Comparison of Technological Characteristics to the Predicate Device:
The DiscCath Needle Set is substantially equivalent in intended use, principles of operation and fundamental technological characteristics to the legally marketed predicate device. The below table summarizes the similarities and differences in design, materials and dimensions between the subject and predicate device.

Comparison with Predicate		**SUBJECT DEVICE**	**PREDICATE DEVICE**
		DiscCath Needle Set	**Pakter Curved Needle Set (K173155)**
Regulation		21 CFR § 868.5150	21 CFR § 868.5150
Product Code		BSP	BSP
Classification		II	II
Indications for Use		The DiscCath and Needle Set is intended to provide access into the intervertebral disc for discography and injection of fluids. The device is intended for adult patients.	The Pakter Curved Needle Set is intended for discography, diagnostic sampling, aspiration, and injection.
Device is for One-time Use		Yes	Yes
Device Configuration		Needle and catheter coaxial set consisting of a 17 gauge stainless steel outer needle and stylet and a 21 gauge flexible curved nitinol needle.	Two needle coaxial set consisting of a 21 gauge stainless steel outer needle and stylet and a 25 gauge flexible curved nitinol needle and stylet
Curved Needle/Catheter	Catheter Material	Nitinol	Nitinol
	Catheter Hub Material	Polymer	Polymer
	Length	26 cm	15, 20 cm
	Size	21 gauge	25 gauge
	Tip Configuration	Curved, with welded blunt tip	Curved 30^{o} bevel
	Distal Opening	One (side) fenestration	End opening

Comparison with Predicate		**SUBJECT DEVICE**	**PREDICATE DEVICE**
		DiscCath Needle Set	**Pakter Curved Needle Set (K173155)**
Introducer Needle/Stylet	Cannula/ Stylet Material	Stainless Steel	Stainless Steel
	Cannula/ Stylet Hub Material	Metal	Acrylic
	Cannula Size	17 gauge	21 gauge (0.82mm)
	Cannula Length	15.24 cm (6 inches)	10, 15 cm
	Needle/Stylet Tip Point Configuration	Bevel ground point needle with an angle of 11°±3° and matched angled tip stylet	Trocar tip with beveled ground point stylet
Packaging		Tray in a pouch	Peel Pouch
Sterilization Method		EtO	EtO
Sterility Assurance Level		10^{-6}	10^{-6}
Non-pyrogenic		Yes	Unknown – Not indicated on labeling

The subject and primary predicate device differ from one another primarily with respect to size, length and end-hole configuration. The differences are bridged when considering other commercially available needles/catheters used for intradiscal procedures. Specifically, similar to the DiscCath Injection Catheter, the SPINECATH Intradiscal Catheter (K993967) is provided with a 17 gauge Introducer Needle offered in lengths up to 9 inches (approx. 23 cm). Similar to the DiscCath Injection Catheter, the IMD Lumbar Puncture Needle (K170112) is also offered with a closed end tip with side port fenestration. Although, the 26 cm DiscCath Injection Catheter is longer than the Pakter Curved Needle Set (provided in lengths of 15 and 20 cm); the length of the catheter is comparable to the SPINECATH device (provided in a length up to approx., 23 cms). The length of the DiscCath Injection Catheter has been selected to allow access to the posterior annulus and does not raise new questions of safety or effectiveness.

Performance Data

Performance testing of the final, sterilized DiscCath Needle Set included bench testing and functional testing to verify specifications fundamental to the design of the device. Testing included the following:

- Visual Inspection of Components
- Dimensional Verification of Components
- Functionality Testing
- Kink Resistance
- Luer Testing per ISO 80369-7:2016 and ISO 80369-20:2015

- Luminal Patency per ISO 7864:2016
- Stiffness (Deflection per ISO 9626 Annex B)
- Component Tensile Strength compared with the predicate Pakter device
- Introducer Cannula and Injection Catheter Resistance to Breakage
- Corrosion Resistance per ISO 11070:2014 Annex B
- Comparative Particulate Testing
- Radiopacity testing in accordance with ASTM F640-12, and
- Packaging Integrity & Shelf-Life Validation

Physician simulated use testing was also conducted to demonstrate the subject device is substantially equivalent to the predicate device. The DiscCath Needle Set met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

Biocompatibility Testing

A biocompatibility evaluation was conducted in accordance with the FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,"* consistent with an externally communicating device with tissue/bone/dentin for a limited duration (≤24 hours). The following biocompatibility tests were successfully completed on the final, sterilized DiscCath Needle Set:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Toxicity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Direct and Indirect Hemolysis

The DiscCath Needle Set does not have direct or indirect contact with cerebrospinal fluid (CSF). A risk assessment was performed to address the potential for neurotoxicity to address this additional biocompatibility endpoint under atypical conditions of use. The catheter is designed with a flexible tip and therefore is unable to penetrate the dura. As the catheter placement and fluid administration procedure is performed under radiologic visualization (fluoroscopy and/or CT) the physician performing the discography would know if the needle/catheter penetrated to the level of the dura and would immediately retract the device. For this reason testing to address neurotoxicity endpoints is not required. In conclusion, the DiscCath Needle Set does not present a risk for contacting CSF and therefore biocompatibility testing presented herein is consistent with FDA/ISO guidance for an externally communicating device with

tissue/bone/dentin for a limited duration (≤24 hours) is sufficient for establishing biological safety of the device for its intended use.

Sterility
The DiscCath Needle Set is sterilized via a validated ethylene oxide (EO) process to a Sterility Assurance Level (SAL) of 10^{-6}. The sterilization process was validated per ISO 11135 *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.* EO residuals were within accepted limits. The bacterial endotoxins test (BET), also known as the Limulus amebocyte lysate (LAL) test, was validated to establish that the DiscCath Needle Set endotoxin level will be < 20 endotoxin units (EU)/device.

Shelf Life
The DiscCath Needle Set has a shelf life of 6-months. Shelf life studies have been conducted to demonstrate that the device maintains its performance and the packaging will maintain its sterile barrier over the entirety of the intended shelf life.

Clinical Performance Data
No clinical studies were deemed necessary to demonstrate the safety and effectiveness of the subject device.

Conclusion
The subject device and the predicate device have the same intended use, and the difference in technological characteristics do not raise different questions of safety and effectiveness.

DiscCath LLC. has demonstrated that the DiscCath Needle Set is substantially equivalent in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use/ indication for use and fundamental technology as the legally marketed predicate device; i.e., the Pakter Curved Needle Set, which was cleared under 510(k) Premarket Notification K173155 on June 7, 2018.