February 6, 2020

Ancora Medical Technology
% Terri Bogucki
Consultant
Decus Biomedical Inc
2342 Shattuck Ave #333
Berkeley, California 94704

Re: K191290
Trade/Device Name: Ancora Nerve Block Catheter Set
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: January 6, 2020
Received: January 8, 2020

Dear Terri Bogucki:

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 ENT, 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191290

Device Name
Ancora Nerve Block Catheter Set

Indications for Use *(Describe)*
The Ancora Nerve Block Catheter Set is indicated for surgical pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The device allows physicians to locate peripheral nerves by transferring electrical impulses from a nerve stimulator and/or through ultrasound visualization of the device. The catheter may remain in dwelling for up to 72 hours.

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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# 5 510(k) Summary

| | |
|---|---|
| **Submitter's Name:** | Ancora Medical Technology |
| **Address:** | 333 Ravenswood Ave<br>Menlo Park, CA 94025 |
| **Contact Person:** | Terese Bogucki |
| **Title:** | Regulatory Consultant |
| **Telephone Number:** | 650-488-7799 |
| **Fax Number:** | 650-227-2264 |
| **Email:** | terri@decusbiomedical.com |
| **Date Summary Prepared:** | 9 May 2019 |
| **Device Proprietary Name:** | Ancora Nerve Block Catheter Set |
| **Model Number:** | 10-04-SET1 |
| **Common Name:** | Peripheral Nerve Block Needle |
| **Regulation Number:** | 21 CFR 868.5150 |
| **Product Code:** | BSP |
| **Device Class:** | II |
| **Predicate Device** | Trade name: Braun Contiplex® C<br>Manufacturer: B Braun Medical Inc.<br>Address: 901 Marcon Boulevard<br>Allentown, PA 18109-9341<br>Regulation Number: 21 CFR 868.5150<br>Regulation Name: Needles, Conduction, Anesthetic, W/Wo introducer<br>Device Class: Class II<br>Product Code: BSP<br>510(k) Number: K121846<br>510(k) Clearance Date: November 20, 2012 |

## *5.1 Description of the Device*

The Ancora Nerve Block Catheter Set is a sterile, single-use, disposable device, intended for delivery of local anesthetic for continuous peripheral nerve blocks, in adult patients.

The Ancora Nerve Block Catheter Set is intended to be placed with the use of nerve stimulation and/or ultrasound guidance. The device has a catheter-over-needle design, which consists of a 21-gauge needle and 18-gauge catheter with a twist lock connection between them. The device design includes an anchor and decoupler to help maintain the catheter position. Both the needle and catheter have NRFit connection for infusion. The device set includes two sizes of dressings.

## *5.2 Intended Use*

The Ancora Nerve Block Catheter Set, consisting of the peripheral nerve block needle, catheter, and related dressing accessory, is intended to provide, via percutaneous administration, continuous and/or intermittent infusion of local anesthetics and analgesics for peripheral plexus anesthesia and pain management.

## *5.3 Indications for Use*

The Ancora Nerve Block Catheter Set is indicated for surgical pain management during the pre-operative, perioperative and post-operative periods associated with general and orthopedic surgery. The device allows physicians to locate peripheral nerves by transferring electrical impulses from a nerve stimulator or through ultrasound visualization of the device. The catheter may remain in dwelling for up to 72 hours.

## *5.4 Summary of Technological Characteristics Comparison*

The Ancora Nerve Block Catheter Set has the same intended use as the Contiplex C Continuous Peripheral Nerve Block Needle (K121846). The proposed device and predicate device both incorporate insulated needles to locate targeted nerve bundles by stimulation or ultrasound guidance in order to perform peripheral nerve block procedures. Both devices are used to place an indwelling catheter in position local to the target nerve and are intended to remain indwelling up to 72 hours. Both devices include a catheter over needle design.

Table 5-1 shows the similarities and differences between the two products. The differences in the technological characteristics of the devices result from the Ancora Nerve Block Catheter Set's features that enable the catheter to remain in position so that the anesthetics or analgesics are delivered to the targeted nerve. The Contiplex C Continuous Peripheral Nerve Block Needle secures the catheter to the patient's skin using the Perifix Pinpad. In the subject device, the decoupler assembly, anchor, and dressing work together to stabilize the catheter and catheter tip. While these characteristics are different, the testing demonstrates that they do not raise new questions of safety or effectiveness.

**Table 5-1. Summary of Technological Characteristics Comparison**

| Technological Characteristic | Predicate | Subject Device | Differences |
|---|---|---|---|
| Design | Catheter over needle | Same | None |

| Technological Characteristic | Predicate | Subject Device | Differences |
|---|---|---|---|
| Echogenic | Yes (catheter) | Yes (needle and catheter) | None - ultrasound can be used with the both devices to determine and confirm the correct catheter placement |
| Needle Gauge | 25G | 21G | The subject device has a larger diameter needle, which makes it easier to control but does not impact clinical use (other similar devices on the market have needles as large as 18G); needle testing has demonstrated it meets standards |
| Needle Length | 190 mm | 100 mm | Minimal - the subject device's shorter needle is easier to manage |
| Needle Type | Straight | Same | None |
| Needle Bevel | 30 degree | Same | None |
| Needle Material | Stainless steel | Same | None |
| Compatible with Nerve Stimulators | Yes –Stimuplex® HNS 12 SENSe nerve stimulators | Yes – used with stimulators with a 2 mm touchproof electromedical connector and delivering a maximum current of 5 mA | None – the subject device uses a standard connector (that can be used with the HNS 12 stimulator); subject device testing has demonstrated the needle can tolerate a much higher current than would be applied clinically |
| Stimulation Wire Conduction Material | Unknown | Copper | Conduction materials do not contact the patient; any material differences would not impact safety or effectiveness |

| **Technological Characteristic** | **Predicate** | **Subject Device** | **Differences** |
|---|---|---|---|
| Needle Electrically Insulated? | Yes – parylene coating insulates the needle (except for the bevel tip) | Yes – catheter construction (effectively 5 layers) insulates the needle (except for the tip) | The predicate device used a coating on the needle, but the subject device has no insulation attached to the body of the needle. While the catheter provides insulation, it isn't adhered to the needle. |
| Catheter Gauge | 19G | 18G | Size difference is minimal |
| Catheter Construction | Polyamide and polyeurethane | Polyimide inner sheath with inner spring coil, Pebax outer sheath | Both devices are echogenic; subject device construction with a coil and air gap between sheaths enhances the catheter's echogenicity |
| Catheter Effective Length | 187 mm | 95 mm | Minimal – shorter catheters are said to make securement easier, reduce the likelihood of catheter knotting, and reduce the potential for the catheter to accidentally leave the sterile field during placement |
| Catheter Tip | Open tapered tip | Open smooth, rounded, tapered tip | Minimal – the shapes of the tips do not impact safety or effectiveness |
| Infusion Set Connector Type | Catheter clamp with yellow connector (likely NRFit) | NRFit | Subject device does not require extra step of attaching clamp to the end of the catheter; NRFit is designed to meet ISO 80369-6, an FDA-recognized consensus standard related to small bore connectors for neuraxial applications. The yellow connector on the predicate implies it is also NRFit. |

| Technological Characteristic | Predicate | Subject Device | Differences |
|---|---|---|---|
| Catheter Fixation | Perifix PinPad is a skin fixation device for the Perifix EF filter (which attaches to and stabilizes the catheter) | Decoupler assembly, anchor and dressing | Testing demonstrates the decoupler and anchor do not impact safety and effectiveness. |
| Infusion Filter | Includes Perifix EF filter (0.2µm) | Not included | Filters are used to address concerns the anesthetic is non-sterile or contaminated, for example, as result of disconnection. However, the two additional connection points have raised clinical concerns that filters actually increase the risk for disconnection and infection. Separate filters are widely available and could be attached to the subject catheter. |
| Compatible Infusion Pump | Luer connector, flow rate maximum 35mL/hr | NRFit connector, flow rate maximum 33 ml/min | Minimal – the subject device's labeling indicates the maximum flow rate supported by the catheter, as does the predicate. Subject devices maximum flow rate is higher than the predicate, and therefore matches or exceeds compatibility. |
| External Dressing | Not included or specified | Small and large dressing sizes provided in set | The dressing serves to protect the skin at the catheter insertion point, contain the decoupler and secure the catheter; standard practice is to apply a dressing over the insertion site. |

| Technological Characteristic | Predicate | Subject Device | Differences |
|---|---|---|---|
| Device Insertion Aid | Control Grip | Ridged edges on the hubs | The moveable Control Grip on the predicate device is intended to facilitate insertion of the needle and catheter together at 2 cm intervals. This is needed because of the predicate's thinner and longer needle.<br>The ridged edges on the subject device's hubs help stabilize the two components during insertion. The subject device's thicker needle does not need additional support for insertion.<br>These differences have no impact on safety and effectiveness. |
| Packaging | Individually packaged kits provided in a case of 5 units | Individually packaged kits provided in dispenser carton of 6 units | Minimal difference in number of units has no impact on safety or effectiveness |

## *5.5 Non-Clinical Performance Data*

Testing was performed with the Ancora Nerve Block Catheter Set to support substantial equivalence to the predicate device. Testing included performance testing, biocompatibility, sterilization, and shelf-life testing.

Performance testing completed included the following functional tests: electrical performance (continuity, current transfer), flow rate, occlusion, kink resistance, resistance to breakage, joint bond strength, leakage, penetration force, echogenicity, corrosion resistance.

The following standards were utilized in the evaluation:

- ISO 20698, Catheter systems for neuraxial application -- Sterile and single-use catheters and accessories
- EN 13868, Catheters - Test methods for kinking of single lumen catheters and medical tubing

- ISO 7864, Sterile hypodermic needles for single use
- ISO 10555-1, Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements
- ISO 10555-5, Intravascular catheters -- Sterile and single-use catheters -- Part 5: Over-needle peripheral catheters
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems

In addition, Ancora Medical Technology conducted performance testing to demonstrate the subject device conforms with the following test standards:

- ISO 80369-6:2016, Small bore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications
- ANSI/AAMI/ISO 11135:2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

Results of performance testing indicate that the needle and catheter, in the Ancora Nerve Block Catheter Set meet applicable sections of the standards referenced and are safe and effective for their intended use. Based upon the results of this testing, it was determined the Ancora Nerve Block Catheter Set performance was substantially equivalent to the predicate device.

### *5.5.1 Biocompatibility Testing*

Biocompatibility testing was performed based on the nature and duration of patient contact outlined in ISO 10993-1: “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” and 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"”. The needle assembly was tested per the ISO 10993-1 requirements for an externally communicating device with tissue contact for a limited duration (< 24 hours). The catheter and the decoupler were tested per the requirements of ISO 10993-1 as an externally communicating device with tissue contact for a prolonged duration (>24 hours to 30 days). The dressing was tested per the requirements of ISO 10993-1 as a skin contacting device with skin contact for a prolonged duration (>24 hours to 30 days). Results of testing demonstrates that the materials used in the construction of the needle and catheter in the proposed Ancora Nerve Block Catheter Set are safe for their intended use.

## *5.6 Substantial Equivalence Conclusion*

An analysis of the subject and predicate devices shows that the Intended Use and Indications for Use, principles of operation, and conditions of use are identical, and that differences in technical characteristics do not raise different questions of safety and

effectiveness. Therefore, one can conclude that the Ancora Nerve Block Catheter Set is substantially equivalent to the predicate Contiplex C Continuous Peripheral Nerve Block Needle device.