510(k) SUMMARY

K101728

AUG 2 5 2010

Submitted By: Sean R. Werner, PhD.
Regulatory Science Associate
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2685
14 May, 2010

Trade Name: Cook Incorporated Focus™ Echogenic Nerve Stimulating Needle

Proposed Classification Name: Needle, Conduction, Anesthetic (W/Wo introducer)

Indications for Use: The Focus™ Echogenic Nerve Stimulating Needle is intended for locating and stimulating peripheral nerves and nerve plexuses for nerve block anesthesia techniques using a Peripheral Nerve Stimulator and/or ultrasound guidance.

Predicate Devices: 22 and 23 Gauge Cook Incorporated Focus Echogenic Nerve Stimulating Needle, 510(k) number K093209.

Device Description: The Focus Needle is a sterile, single use FEP-coated stainless steel needle with a B Bevel tip. The needle contains black marker bands every 10 mm to aid in placement and echogenic dimpling on the distal 10 mm to enhance visibility under ultrasound guidance. An insulated wire is attached to the stainless steel cannula and can be connected to a peripheral nerve stimulator unit. The device will be available in the following gauge sizes: 20, 21, 22 and 23.

Substantial Equivalence:
The 20 and 21 Gauge Focus Echogenic Nerve Stimulating Needles are substantially equivalent to the predict 22 and 23 Gauge needles.

Test Data:

The following tests were conducted to demonstrate reliable design and performance of the Focus Needle:

- Leakage,
- Tensile strength,
- Cannula break strength,
- Penetration force,
- Sterilization testing,
- Biocompatibility testing.

The results of these tests provide reasonable assurance that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Sean Werner
Regulatory Science Associate
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

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Re: K101728
Trade/Device Name: Focus™ Echogenic Nerve Stimulating Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: July 23, 2010
Received: July 26, 2010

Dear Mr. Werner:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101728

Indications for Use

510(k) Number (if known): _____

Device Name:

Focus™ Echogenic Nerve Stimulating Needle

Indications for Use:

The Focus™ Echogenic Nerve Stimulating Needle is intended for locating and stimulating peripheral nerves and nerve plexuses for nerve block anesthesia techniques using a Peripheral Nerve Stimulator and/or ultrasound guidance.

Prescription Use XX OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101728