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5. 510(k) Summary

FEB 2 6 2010

Cook Incorporated
Focus™ Echogenic Nerve Stimulating Needle
510(k) Summary
21 CFR 807.92

1. Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Phone Number:	(800) 468-1379
Fax Number:	(812) 332-0281
Contact:	Sean Werner, PhD
Contact Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	812-339-2235 x2685
Contact Fax Number:	812-332-0281

2. Device Information:

Trade name:	Focus™ Echogenic Nerve Stimulating Needle
Common name:	Needle, Conduction, Anesthetic (W/Wo introducer)
Classification:	Class II
Regulation:	21 CFR § 868.5150 Anesthesia Conduction Needle
Product Code:	BSP

3. Predicate Devices:

Cook Incorporated's Focus Echogenic Nerve Stimulating Needle (hereafter referred to as the Focus Needle) is substantially equivalent to the EchoStim Facet Tip Needle manufactured by Hakko Medical Co., Ltd. of Japan and distributed in the U.S. by Havel's Inc. under 510(k) clearance K063380. The Focus Echogenic Nerve Stimulating Needle is also substantially equivalent to the Temena Hybrid Nerve Location Needle manufactured by TE ME NA under 510(k) clearance K080603.

4. 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: 22 and 23.

5. Intended 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.

6. Technological Characteristics:

The Focus Needle consists of a stainless steel cannula coated with a fluorinated ethylene propylene polymer to provide resistance to loss of electrical current along the shaft of the needle, a plastic hub with an attachment point for a connection tube, and an insulated wire attached to the cannula to allow connection to a nerve stimulator unit. Additionally, the distal 10 mm of the needle are dimpled using a pattern designed to enhance visibility by ultrasound. The technological characteristics of the Focus Needle and the two predicate devices, the EchoStim Facet Tip Needle and the Temena Hybrid Nerve Location Needle are substantially equivalent in that all devices are coated with an electrically resistant polymer to allow for electric nerve stimulation, and all devices can be visualized with ultrasound technology. No new technological aspects are being introduced with the proposed device.

To demonstrate reliable design and performance of the Focus Needle, the following verification testing was performed:

- Air leakage under vacuum,
- Fluid leakage under pressure,
- Force to remove protector,
- Needle to hub bond strength,
- Wire to electrical connector bond,
- Wire tensile strength,
- Wire to hub tensile strength,
- Cannula break strength,
- Penetration force,
- Sterilization testing,
- Biocompatibility testing.

Additionally, an evaluation in an animal model was carried out to verify that electrical current applied through the Focus Needle by a Peripheral Nerve Stimulator unit can stimulate a nerve.

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

Dr. Sean Werner
Regulatory Science Associate
Cook, Incorporated
750 Daniels Way PO Box 489
Bloomington, Indiana 47402

FEB 2 6 2010

Re: K093209
Trade/Device Name: Focus™ Echogenic Nerve Stimulating Needle
Regulation Number: 21CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: February 19, 2010
Received: February 22, 2010

Dear Dr. 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

4. Indications for Use Statement

510(k) Number (if known): K093209

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 ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

510(k) Number: K093209