MAR 2 1 2003

7.0 510(k) Summary K021033

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2375

Contact: Sheri L. Musgnung, RA Manager

DEVICE NAME: Stimuplex® STIM-DIG-RC Nerve Stimulator

COMMON OR USUAL NAME: Nerve Stimulator

DEVICE CLASSIFICATION: Class II, 21 CFR 868.2275: Stimulator, Nerve, Battery Powered

PREDICATE DEVICE: B. Braun Medical Inc. Stimuplex® Nerve Stimulator

DESCRIPTION: The modified Stimuplex®-DIG-RC Nerve Stimulator consists of a hand held remote control unit with separate finger rings for the remote control. The STIM-DIG RC consists of a closed circuit led, a current regulator, an internal connection for electrode cable, a frequency switch, and a battery led. The digital display indicates the current settings.

INTENDED USE: The Stimuplex®-DIG-RC Nerve Stimulator is intended for use with B. Braun Medical Inc. Stimuplex and Contiplex® insulated needle sets for use in regional anesthesia and regional pain therapy. Peripheral nerves are stimulated and located via electrical current impulses flowing through an insulated needle.

SUBSTANTIAL EQUIVALENCE: The modifications that were made to the STIM-DG-RC do not affect the indication for use and does not alter the fundamental technology of the device. The operation and function of the unit remains the same. The risk analysis method used to access the impact of the modifications was a Failure Modes and Effects Analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Ms. Sheri L. Musgnung
B. Braun Medical, Incorporated
901 Marcon Boulevard
Allentown, PA 18109-9341

Re: K021033
Trade/Device Name: Stimuplex®-DIG-RC Nerve Stimulator
Regulation Number: 868.2775
Regulation Name: Battery Powered Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: March 13, 2003
Received: March 14, 2003

Dear Ms. Musgnung:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K021033

Device Name: ~~Stimuplex~~ Stimuplex -Dig-RC NERVE STIMULATOR

Indications For Use:

The Stimuplex®-DIG-RC Nerve Stimulator is intended for use with B. Braun Medical Inc. Stimuplex and Contiplex® insulated needle sets for use in regional anesthesia and regional pain therapy. Peripheral nerves are stimulated and located via electrical current impulses flowing through an insulated needle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Jan E Harris 3/21/03
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021033