Annex II

K061983

NOV 2 1 2006

Stockert GmbH

# 510(k) Summary

November 9, 2006

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Contact: Dominika Schuler, Management Representative

Trade Name: Stimuplex® Pen

Common Name: Device for cutaneous electrical nerve stimulation

Classification Name:
Neurological Devices, Class II, GXY
Cutaneous electrode
21 CFR 882.1320

Predicate Device: Nerve Mapping Probe *(accessory only)*
for NeuroTrace III Nerve Stimulator
K023342

Superficial nerves can be stimulated electrically through the skin by means of a weak current. Cutaneous electrical nerve stimulation (CENS) represents a decisive advance in the location of superficial nerve structures: it enables the cutaneous projection of any superficial nerve to be determined and the point of needle entry to be optimized in order to more easily perform peripheral nerve block in adults and children.
The Stimuplex® Pen is an electrode for cutaneous stimulation which, when connected to the Stimuplex® HNS 11 or HNS 12 nerve stimulator and placed on the skin, it conducts electrical impulses which initiates muscular contractions and/or synchronous electrical paresthesia whitin the distribution area of a nerve. The nerve passes perpendicularly to the place where a response is observed at the lowest level of current. This designated point of needle entry is situated directly perpendicular with the nerve.

Stimuplex® Pen is intended to be used only with B.Braun's nerve stimulators: Stimuplex® HNS 11 (510k no. K003983) and/or Stimuplex® HNS 12 (510k no. K052313).

The configuration of the electrode connection is realized with a 1 pin plug safety connection system, which ensures correct polarity of the electrode to the Stimuplex® HNS 11 or HNS 12 nerve stimulator. The nerve stimulator generates negative, current-stabilized square pulses with selectable frequency, selectable pulse width and fine adjustable stimulation current. It displays the actual stimulation current so that the proper current flow can be checked.

The intended use is a cutaneous stimulation electrode for locating superficial peripheral nerves through the skin in local/regional anaesthesia, local/regional analgesia and neurology. Stimuplex® Pen is a prescription use only device, the patient is not the operator. It can be used on adult, pediatric, and/or infant population

The general technological characteristics of the Stimuplex® Pen are generally equivalent in materials, form and intended use to the Nerve Mapping Probe (accessory only) for the NeuroTrace III peripheral nerve stimulator. Differences between the Stimuplex® HNS 12 and the predicate device consist only in the nerve stimulation parameters of the nerve stimulators and the diameter of the tip. The small power density difference doesn't affect safety and effectiveness for the intended use.

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release includes, but is not limited to: physical testing, visual examination (in process and finished product). The physical testing is defined by quality control test procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications. The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control GMP's.

signed: _____ date: 2006-11-09

Dominika Schuler, Management Representative
Stockert GmbH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dominika Schuler
Management Representative
Stockert GmbH
Boetzinger Strasse 72
Freiburg, B-W,
GERMANY, D-79111

NOV 2 1 2006

Re: K061983
Trade/Device Name: Stimuplex Pen
Regulation Number: 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: November 9, 2006
Received: November 13, 2006

Dear Ms. Schuler:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Annex I

# Indications for Use

510(k) Number (if known): K061983

Device Name: Stimuplex Pen

Indications for Use:

Stimuplex® Pen is a cutaneous stimulation electrode for locating superficial peripheral nerves through the skin in local/regional anaesthesia, local/regional analgesia and neurology. It is a non invasive device.

Intended patient population: for adult, pediatric and/or infant use.

Stimuplex® Pen is intended to be used only with B.Braun's nerve stimulators: Stimuplex® HNS 11 (510k no. K003983) and/or Stimuplex® HNS 12 (510k no. K052313).
It can be used wherever peripheral anesthesia is normally applied (i.e. physician's office or hospital).

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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) K061983