K070134

MAR 2 2 2007

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510(k) Summary

February 9th, 2007

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® HNS 12

Common Name: Battery powered peripheral Nerve Stimulator

Classification Name:
Anesthesiology Devices, Class II, 73 BXN
Battery Powered Nerve Stimulator
21 CFR 868.2775

Predicate Device: Stimuplex® HNS 11
K052313

The nerve stimulator Stimuplex® HNS 12 is a battery powered peripheral nerve stimulator for localization of nerve fibers in the tissue. During the operation the operating physician holds a stimulation cannula in his right hand. Simultaneous the operation of the device happens with his left hand. The physician can hold the device with the left hand and simultaneous alter the stimulation amplitude at the amplitude controller.

The technical data of the device are:

Battery:	9 Volt alkaline
Display:	1 graphic LCD Module
	1 tricolor (green, yellow, red) LED for status display
Operation:	1 control button to switch on/off the device
	Adjustment knob to adjust the wanted stimulation current
	3 control buttons to switch the stimulation parameters
	4 control buttons for navigation and settings in the menus
	Remote control (optional stimulation current adjustment)
Power consumption:	6 mA (8 mA max in warning/alarm state)
Stimulation current :	max. 5mApp / 0Ω - 12 kΩ
Stimulation voltage :	max. 95 Vpp
Stimulation frequency :	1 Hz / 2 Hz
Flowing current measuring tolerance:	+/- 0.02 mA
Weight:	0.25 kg (with battery)

The configuration of the electrode connection is realized with a 4 pin plug connection system, which ensures correct polarity of the electrode at all times. The Stimuplex® HNS 12 generates negative, current-stabilized square pulses with selectable frequency, selectable pulse width and fine adjustable stimulation current. The pulse is shaped at both slopes by extremely fast active pulse drivers. An output amplifier specially designed for this application has an extraordinarily wide dynamic range and produces reproducible settings even below 0.1 mA. The stimulation frequency and the pulse width can be varied for different applications. The Stimuplex® HNS 12 nerve stimulator offers the facility for selecting a frequency of either 1 Hz or 2 Hz together with pulse widths of 0.1 ms, 0.3 ms or 1.0 ms. Two additional pulse widths: 0.05 ms and 0.50 ms can be enabled in options menu. Stimuplex® HNS 12 has a menu structure (in 26 languages) where the switch on parameters and options and setup parameters like tone volume, contrast, automatically switch off time, language can be configured. The battery voltage is in info menu in volt and percentage and during stimulation menu as symbol displayed.

The intended use is a peripheral nerve stimulator to test the level of pharmacological effect of anesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anesthetics. This device can be used wherever peripheral anesthesia is normally applied (i.e. physicians office or hospital). There are no known contraindications for the use of this device on any patient population.

The fundamental scientific technology and the characteristics of the modified Stimuplex® HNS 12 are entirely equivalent in materials, form and intended use to the predicate device. The only diference between the modified Stimuplex® HNS 12 and the predicate device consist in additional accessories *Stimuplex® Switch* alternative electrode cable for ergonomic connecting of the stimulation needle or the stimulation catheter. The intended use of the modified Stimuplex® HNS 12 has not changed as a result of the modification.
The Stimuplex® HNS 12 is highly specific for its intended use in anesthesiology. The instruction of the *Stimuplex® Switch* 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 include, but are 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: D. Schuler date: 2007-02-20

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 Respresentative
Stockert GmbH
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D-79111 Freiburg
GERMANY

MAR 2 2 2007

Re: K070134
Trade/Device Name: Stimuplex® HNS 12
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: February 20, 2007
Received: February 26, 2007

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.

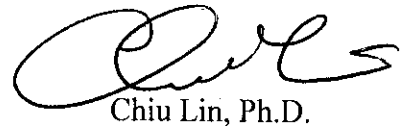
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known):

Device Name: Stimuplex ® HNS 12

Indications for Use:

Stimuplex® HNS 12 is a peripheral nerve stimulator used to test the level of pharmacological effects of anaesthetic drugs and gases to the patient and/or as a nerve locator for the verification of needle placement for the application of local anaesthetics. This device can be used wherever peripheral anaesthesia is normally applied (i.e. physicians office or hospital). Intended patient population: for adult, pediatric and/or infant use.

This is the **same intended use** as previously cleared for the Stimuplex® HNS 12, 510(k) Number K 052313, date 2005-11-17.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chl [signature]

...General Hospital, ...on Control, ... Devices

...Number K070134