K023342

MAR - 2 2004

510(k) Summary
NeuroTrace III

Name of Device:	NeuroTrace III
Common or Usual Name:	Stimulator, Nerve, Peripheral, Electrical
Classification Name:	Electrical Peripheral Nerve Stimulator
CFR Section:	21 C.F.R. § 868.2775
Product Code:	KOI
Submitter:	HDC Corporation 628 Gibraltar Court Milpitas, CA 95035
Phone Number:	(408) 942-7340
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Contact Person:	Earl Smart
Alternate Contact Person:	Jonathan Kahan, Esq. Hogan & Hartson, L.L.P. 555 Thirteenth Street, NW Washington, DC 20004-1109 (202) 637-5794 - Telephone (202) 637-5910 – Facsimile

Predicate Devices:

Fisher & Paykel Innervator 242 - K883868
Fisher & Paykel Innervator 252 - K882438
Organon Teknika TOF Watch S - K992596
Life-Tech MaxiStim - K955031

Intended Use/Indications:

The NeuroTrace III can be used as an objective monitor using accelerometry for measuring the muscle contraction following stimulation of the respective motor neuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and for locating specific nerves. It is particularly useful in nerve block procedures to obtain effective regional anesthesia blocks.

Substantial Equivalence:

The NeuroTrace III has the same intended use and indications for use as a combination of predicate devices. Specifically, it is intended for nerve location and indicated to be used as an objective monitor using accelerometry for measuring

the muscle contraction following stimulation of the respective motor neuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and for locating specific neurons. The NeuroTrace III is particularly useful in nerve block procedures to obtain effective regional anesthesia blocks. Similarly, the NeuroTrace III and the predicate devices have the same principles of operation and technological characteristics, including a current range from 1 to 60 mA into resistance values ranging from 0.5 to 5.0 kiloOhms, maximum power output across the range of currents and resistance values, the use of an accelerometer to measure muscle contraction, and a post-Tetanic stimulation duration of up to 5 seconds. Thus, the NeuroTrace III can be found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2004

HDC Corporation
C/O Mr. Jonathan Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K023342
Trade/Device Name: NeuroTrace III Kit, NeuroTrace III Regional Block Cable, NeuroTRace III Nerve Mapping Probe, NeuroTrace Nerve Monitoring Cable, NeuroTrace III Accelerometer Cable
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: KOI
Dated: January 29, 2004
Received: January 29, 2004

Dear Mr. Kahan:

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,

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): K023342

Device Name:

NeuroTrace III Kit, NeuroTrace III Regional Block Cable, NeuroTrace III Nerve Mapping Probe, NeuroTrace Nerve Monitoring Cable, NeuroTrace III Accelerometer Cable

Indications for Use:

The NeuroTrace III can be used as an objective monitor using accelerometry for measuring the muscle contraction following stimulation of the respective motor neuron, as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring and for locating specific nerves. It is particularly useful in nerve block procedures to obtain effective regional anesthesia blocks.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/27/2004

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

510(k) Number K023342