JAN 2 4 2003

K 022433

510 (k) Summary

- Trade name – NEO GeneSys 2k
- Classification name – Interferential Current Therapy device, Product Code LIH (Unclassified), IPF, GZJ

The legally marketed device to which our firm is claiming equivalence is the ProElecDT, K930263. [807.92(a)(3)].

Description and Intended Use [807.92(a)(4)] and [807.92(a)(5)]
This device is an electrical signal generator which applies sinusoidal current through two pairs of contact electrodes using temporal interference patterns to stimulate peripheral nerves for the purpose of providing pain relief or as an adjunctive treatment in physical therapy per guidelines in the indications for use. As an alternative, this device can perform the forementioned functions by applying sinusoidal current through only one pair of electrodes.

Summary of the technological characteristics [807.92(a) (6)]
There is no difference in technological characteristics between this device and the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Sanexas International GmbH
C/o Mr. Gene Kelly
Regulatory/Clinical Consultants, Inc.
200 NE Mulberry, Suite 200
Lee's Summit, MO 64086

Re: K022433
Trade/Device Name: NEO GeneSys 2k
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, LIH, GZJ
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Kelly:

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) 594-4639. 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,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D. Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022433

Indications for Use

NEO GeneSys 2k

PAIN MANAGEMENT

Indications for Electromedical Treatment

1. For adjunctive treatment of post-traumatic pain syndromes.
2. For management and symptomatic relief of chronic (long-term) intractable pain.
3. As an adjunctive treatment in the management of post-surgical pain problems.

MUSCLE STIMULATION

Indications for Electromedical Treatment

1. Relaxation of muscle spasms.
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle reeducation
5. Immediate post-surgical stimulation of calf muscle to prevent phlebothrombosis.
6. Maintaining or increasing range of motion

Powered Muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

for Mark N. Milkens

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022433