K-11

Stockert GmbH

510(k) Summary

2007-01-31

K070336

Bötzinger Straße 72
79111 Freiburg
phone: ++49-761-20716-0
Fax: ++49-761-20716-20
eMail: info@stockert.de
http://www.stockert.de

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, Business Manager
Trade Name:	STOCKERT NEURO N50
Common Name:	Radiofrequency Lesion Generator
Classification Name:	Generator, Lesion, Radiofrequency 21 CFR 882.4400, Product Code GXD, Class II
Predicate Device:	NEURO N 50 LESION GENERATOR 510(k) No. K896450
Description:	The system consists of a radio frequency generator and accessories intended for neurological applications. Its purpose is to generate RF energy for delivery to a site in neurological tissue via a neurological instrument for a specified time period. The thermal energy emitted at the site of application produces a lesion that interrupts an electrical active area of neurological tissues. The STOCKERT NEURO N50 can be used either in bipolar or unipolar mode and includes functions for controlling temperature at the tip of the instrument and for monitoring impedance. It also has a unit for stimulation for provoking, localized, blocking and intraoperative test stimulation.

signed: D. Schuler date: 2007-01-31

Dominika Schuler, Business Manager
Stockert GmbH

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stockert GmbH
% Ms. Dominika Schuler
Business Manager
Bötzinger Straße 72
79111 Freiburg
Germany

JUN 14 2007

Re: K070336
Trade/Device Name: STOCKERT NEURO N50
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD
Dated: May 16, 2007
Received: May 16, 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) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070336

Device Name: STOCKERT NEURO N50

Indications for Use:

Stockert NEURO N50 is a RF generator for general high frequency applications:

1. Lesioning nerve tissue for functional neurosurgical procedures; or
2. Radiofrequency heat lesion procedures for the relief of pain; or
3. Stimulation procedures like provoking stimulation, localized stimulation, blocking stimulation or intraoperative test stimulation

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)

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

510(k) Number K070336