

MAY 18 2006

Page 1 of 2

510 (k) SUMMARY

K 061258

Applicant

NeoMedix Corporation
15042 Parkway Loop, Ste. A
Tustin, CA 92780

Contact Person

Thomas Schroeder
VP, RA/QA
Phone (714) 290-5720
FAX: (949) 646-8177
e-mail: tschroeder@neomedix.net

Common, Classification and Proprietary Names

Common Names: Electrosurgical Generator

Classification Name: Electrosurgical cutting and coagulation device, 21 CFR 878.4400, Product Code GEI.

Proprietary name: Trabectome™ High Frequency Generator/LP

Predicate Device

The NeoMedix Corporation Trabectome™ High Frequency Generator/LP is substantially equivalent in design, construction and features to the Aaron Medical Model 800 High Frequency Desiccator cleared under K955681. Both devices operate in either the monopolar or bipolar mode at an operating frequency of ~ 500 kHz. There are no technological differences between the two devices other than the maximum power output. The Aaron 800 generator has a maximum power output of 30 watts while the Trabectome™ High Frequency Generator/LP has a maximum power output of 6 watts.

K 061258

Page 2 of 2

Indications for Use

The Trabectome™ High Frequency Generator/LP is for use with compatible electrosurgical instruments in low power microsurgical applications for the removal, destruction and coagulation of tissue.

Device Description

The Trabectome™ High Frequency Generator/LP is a non-sterile, reusable electrosurgical generator. The device is designed to generate high frequency (radiofrequency "RF") high voltage and low amperage current. The device operates in either the monopolar or the bipolar mode. The device is available in two voltage models: 110 VAC or 220 VAC (for international use). The generator is activated through an input jack on the front panel. The activation can be via a footswitch or other single pole closure device with a compatible plug.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2006

NeoMedix Corporation
c/o Ms. Michelle S. Lee
Underwriters Laboratories Inc.
2600 NW Lake Road
Camas, Washington 98607

Re: K061258

Trade/Device Name: Trabectome™ High Frequency Generator/LP
Regulation Name: Electrosurgical cutting and coagulation device
Regulatory Class: II
Product Code: GEI
Dated: May 1, 2006
Received: May 5, 2006

Dear Ms. Lee:

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" (21 CFR 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,


for

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 STATEMENT

510(k) Number (if known): K061258

Device Name: Trabectome™ High Frequency Generator/LP

Indications for use: The Trabectome™ High Frequency Generator/LP is for use with compatible electrosurgical instruments in low power microsurgical applications for the removal, destruction and coagulation of tissue.

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)

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

510(k) Number K061258