APR 2 2 2004

K040584

Page 1 of (2)

SECTION 2 – 510 (K) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

Date Prepared: February 9, 2004

Manufacturer and Submitter

NeoMedix Corporation
27452 Calle Arroyo
San Juan Capistrano, California 92675
Phone: (949) 248-7029
Fax: (949) 248-7119

Contact Person

Dr. Soheila Mirhashshemi

Common, Classification and Proprietary Names

Common Name: Electrosurgical electrode

Classification Name: Radio frequency cautery device (21 CFR section 886.4100)

Proprietary name: NMX-1000™

Predicate Devices

The NeoMedix NMX-1000™ is identical to the NeoMedix Microsurgical Bipolar Handpiece (K024304; GEI and HQR) in general indications, materials, design and features for ophthalmic surgery. The NeoMedix NMX-1000™ is substantially equivalent in terms of medical intent to the Storz Goniotomy knife [510(k) exempt].

Indications for Use

The NMX-1000™ is designed to surgically remove a strip of the Trabecular meshwork for surgical management of infantile and adult glaucoma.

Device Description

The NMX-1000™ is a sterile single use device that consists of a bipolar probe and channels for irrigation and aspiration. These channels are connected to medical grade tubing with standard luer fittings. The device handpiece is ABS plastic and incorporates a stainless steel probe designed to operate in the bipolar mode when connected to a compatible electrosurgical generator capable of low energy output control. The supplied irrigation and aspiration sets provide for connection of the handpiece to standard irrigation and aspiration devices.

Technological Characteristics Comparison

The probe is identical in design to the currently marketed NeoMedix MicroSurgical Bipolar Handpiece in that the application of radio frequency current is bipolar in nature and occurs at the probe tip. The irrigation and aspiration capabilities are the same as those of the MBH and similar to that of the Storz Maumenee Goniotomy knife cannula. The cutting capability of radio frequency electrosurgical devices is well known and yields a similar result to that of the Goniotomy knife. The construction materials used have an established history of safe use in similar medical devices.

Performance and Safety

The biological safety of the device has been demonstrated through biocompatibility studies of all patient contact materials in accordance with the standards outlined in ISO 10993-1. Electrical safety has been demonstrated by compliance to applicable requirements defined in IEC 60601-1 for leakage current and ANSI/AAMI HF-18 for handpiece dielectric voltage. Physical testing was performed to assure connector integrity, tip bend resistance and fluidic flow capability. Comparative studies on human and animal tissue demonstrate results equivalent to predicate devices. The device is supplied sterile and sterility will conform to a Sterility Assurance Level (SAL) of 10^{-6}. The supplied instructions for use provide the user with the applicable warnings and cautions during use. The device is contraindicated for closed angle glaucoma. Since the device is currently cleared for ophthalmic use and yields a result equivalent to that of a Goniotomy knife, there are no new safety or effectiveness issues related to this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Neomedix Corporation
c/o Mr. Marc M. Mouser
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, Washington 98607

Re: K040584
Trade/Device Name: NMX-1000™
Regulation Number: 21 CFR 878.4400, 886.4100
Regulation Name: Electrosurgical cutting and coagulation device and accessories; Radiofrequency electrosurgical cautery apparatus
Regulatory Class: II
Product Code: GEI, HQR
Dated: April 6, 2004
Received: April 8, 2004

Dear Mr. Mouser:

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) 594-4659. 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 Miriam C. Provost

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040584

Device Name: NMX-1000™

Indications for use: The NMX-1000™ is designed to surgically remove a strip of the Trabecular meshwork for surgical management of infantile and adult glaucoma.

Prescription Use: X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: _____ (Part 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)

Miriam C. Provost

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

510(k) Number K040584