K024304

FEB 25 2003

SECTION 2 – 510 (k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

Date Prepared: November 25, 2002

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 Mirhashemi

Common, Classification and Proprietary Names

Common Name:	Electrosurgical electrode
Classification names:	Electrosurgical cutting and coagulation device and accessories (21 CFR section 878.4400) and Radio frequency cautery device (21 CFR section 886.4100)
Proprietary Name:	Microsurgical Bipolar Handpiece

Predicate Devices

The NeoMedix MicroSurgical Bipolar Handpiece is similar in indications, design and features to the following currently marketed devices: Bipolar probes by Medtronic (K010487), Kirwan (K962678), Xomed (K993655), Oratec (K991218) and Mentor (K971538), Storz Bipolar Cautery Probe (K952151), Ethicon Bipolar Device (K003587) and Wolf Multifunction Instrument (K002000).

Indications for Use

The NeoMedix MicroSurgical Bipolar Handpiece is to be used in electrosurgical applications where low power radio frequency current is applied through a bipolar probe for the purpose of cutting and coagulation of soft tissues. The Handpiece is intended to be used in general and ophthalmic surgery where low impedance or wet field conditions exist.

Device Description

The Handpiece 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 Handpiece is ABS plastic and incorporates a stainless steel probe designed to operate in the bipolar mode when connected to any compatible bipolar electrosurgical generator capable of low energy output control. The irrigation and aspiration sets provide for connection of the handpiece to irrigation and aspiration devices.

Technological Characteristics Comparison

The probe is similar in design to currently marketed bipolar probes (Mentor, Kirwan, Storz) in that the application of radio frequency current is bipolar in nature and occurs at the probe tip. The basic coaxial electrode design has been modified to include a protective foot to shield underlying tissue from current flow. This modification does not affect the safety or effectiveness of the device. A polyimide electrode insulation material provides the electrical isolation between the active and return bipolar electrodes. The irrigation and aspiration capabilities are similar to those in the Richard Wolf Multifunction Instrument. The bipolar electrical connector pins are compatible with standard bipolar cables that connect to an electrosurgical radio frequency generator, such as those used for the Storz, Mentor, Kirwan probes. 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. 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. There are no known contraindications. 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

FEB 2 5 2003

Underwriters Laboratories, Inc.
Robert M. Boonstra
Senior Staff Engineer
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K024304
Trade/Device Name: MicroSurgical Bipolar Handpiece
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories;
Regulatory Class: Class II
Product Code: GEI; HQR
Dated: February 7, 2003
Received: February 11, 2003

Dear Mr. Boonstra:

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). Other general information on your responsibilities under the Act may be obtained 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 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~~): K024304

Device Name: MicroSurgical Bipolar Handpiece

Indications for use: The NeoMedix MicroSurgical Bipolar Handpiece is to be used in electrosurgical applications where low power radio frequency current is applied through a bipolar probe for the purpose of cutting and coagulation of soft tissues. The Handpiece is intended to be used in general and ophthalmic surgery where low impedance or wet field conditions exist.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-the-counter: _____

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative

510(k) Number K024304