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SECTION 2 – 510 (k) SUMMARY

SUMMARY INFORMATION

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: Suction Pump

Classification names: Powered suction pump.

Proprietary Name: SupraFlow Console

Predicate Devices

The NeoMedix SupraFlow Console Model numbers 550014, 550019, 550020 are similar in indications, function and features to the following Devices: The Karl Storz KSEA Unimat 45 (K981703), the XOMED Tissue Aspiration System (K984363) and the Lysonix Aspiration Pump (K980454).

Indications for Use

The NeoMedix SupraFlow Console is to be used in general surgery applications where aspiration of irrigation fluid from a surgical site is desired. The device is not indicated for liposuction use.

Device Description

The Console contains a roller pump to provide aspiration from the surgical site and a pinch valve to initiate the flow of irrigation fluid simultaneously with the initiation of aspiration. The optional foot switch can be used to activate both actions.

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Technological Characteristics Comparison

The Console is similar in function to currently marketed aspiration/suction pumps. The aspiration capabilities are similar to those in the predicate devices with the exception that suction is generated via peristaltic action rather than a direct vacuum source. The Console is powered by 12VDC provided by a medical grade external 90 - 240 VAC, 50/60 Hz power supply.

Performance and Safety

Electrical safety has been demonstrated by compliance to applicable requirements defined in consensus standard IEC 60601-1. Product testing was performed to demonstrate stated performance specifications and functionality in compliance with NeoMedix test protocols. The supplied Operations Manual provides the user with the applicable warnings and cautions during use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2004

Neomedix Corporation
c/o Mr. Marc M. Mouser
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K040239
Trade/Device Name: SupraFlow Console
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: January 29, 2004
Received: February 2, 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,

Miriam C. Provost

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): K040239

Device Name: SupraFlow Console

Indications for use: The NeoMedix SupraFlow Console is an aspiration pump intended for use in general surgery applications where aspiration of irrigation and waste fluid from a surgical site is desired.

The device is not indicated for liposuction use.

(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: _____

Miriam C Provost

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

510(k) Number K040239