

K980627

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**510(k) SUMMARY
of
SAFETY and EFFECTIVENESS**

A. General Information

1. *Submitter's Name:* UroMetrics, Inc.
2. *Address:* 445 Etna Street, #56
St. Paul, MN 55106
3. *Telephone:* 612-774-1552
4. *Contact Person:* Philip A. Messina
5. *Date Prepared:* February 16, 1998
6. *Registration Number:* 2134152

B. Device

1. *Name:* NEVA™ System
2. *Trade Name:* NEVA™ System
3. *Common Name:* Penile Tumescence Monitor
4. *Classification Name:* Penile Tumescence Monitor
5. *Product Code:* 78 LIL
6. *Class:* II
7. *Regulation Number:* None

C. Identification of Legally Marketed Device

1. *Name:* RigiScan® Plus System
2. *K Number:* K941781
3. *Date Cleared:* August 25, 1994

D. Description of the Device

The UroMetrics NEVA system consists of three disposable electrodes sets, a portable battery powered recorder, a host interface, cables and a computer program. Two of the three electrode sets are placed on the penis so that one electrode set is on the glans terminating just proximal to the glans, one set is at the base of the penis terminating a fixed distance from the base of the penis. The third electrode is attached to the patient's hip. The wires from the electrodes terminate in a phone connector which plugs into the portable NEVA recorder.

The electrodes and the recorder are used by the patient to monitor nocturnal tumescence for up to three nights. The host interface and the computer program are used to prepare (initialize) the recorder for use and to download the data from the recorder for display and analysis on a physician's computer.

The NEVA system indicates penile tumescence by monitoring changes in volume, length and area. Due to a variety of factors (patient position, etc.) the size of the penis can change its shape. An increase in length, by itself, may not indicate tumescence. Tumescence is generally indicated by an increase in volume, length and area. This is the primary reason the NEVA system displays volume, length and area throughout the test.

Impedance values which are used to determine penile volume, length and area are continuously recorded at one second intervals. The one second time base and the change in volume data allow a physician to determine the fill rate once periods of tumescence are identified.

The NEVA system determines changes in volume by measuring the impedance within the penis. A low powered alternating current is sent from the electrode on the glans to the ground electrode on the hip. The remaining electrodes are used to measure the impedance. The electrode set at the

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base of the penis includes electrodes which are separated by a fixed distance. As the cross-sectional area of the blood volume in the penis increases, there is a decrease in measured impedance in the base electrode set. These impedance changes are then converted to a volume reading by the host computer. With an increase in distance between the base electrode and the electrode posterior to the glans (penis length) there is an increase in the impedance between these electrodes. This change in impedance is converted to a length reading.

To begin a test, the NEVA recorder is plugged into a computer through the host interface to a host computer running the NEVA software. The computer and software will recognize the recorder and will display a menu which allows the physician to download previously recorded data or initialize the recorder for a new test. To begin a new test, the physician enters the patient's name and other information and initializes the recorder. All previous data are cleared and the patient information is saved to the recorder.

The NEVA software allows the physician the option of real time measurements while connected to the computer. This capability is useful to demonstrate the proper placement of the electrodes and to check for proper operation. Once the NEVA recorder is initialized and the patient is instructed in its use, the recorder and electrodes are sent home with the patient. The electrodes are designed for single use so a separate set of electrodes is needed for each night (sleep period) of the test.

The NEVA recorder is normally in standby mode until the electrodes are placed on the patient and the connector is plugged into the recorder. When the connector is removed the recorder returns to the standby mode. Patients should be instructed to plug in the electrodes at the beginning of the test and unplug the electrodes at the end of the test. The recorder can store data for a maximum of 36 hours, typically three sleep periods.

At the end of the test period, the NEVA recorder is plugged into a computer through the host interface to a host computer running the NEVA software. The computer and software will recognize the recorder and will display a menu which allows the physician to download the data.

The data are then downloaded to the computer and stored on the computer's hard drive. The impedance data are converted to volume, length and cross-sectional area plots which are displayed graphically on the computer screen.

The software incorporates a number of features which facilitate the analysis and interpretation of the data by the physician.

The NEVA™ System has many components and accessories. Components are pieces of the NEVA™ System unit which are necessary to perform any reading of nocturnal tumescence. Accessories are additional equipment that allow for more efficient recordings.

NEVA™ System Components

- Recorder
- Electrode Sets

NEVA™ System Accessories

- Cables
- Computer Program
- Carrying Cases (Physician and Patient)
- Electrode Harness
- Isolation Box
- Leg Strap and Bag
- Power Adapter
- 9-Volt Batteries
- Patient Manual
- Physician's Operator Manual

E. Intended Use Statement

The NEVA™ System is an device to measure and record penile erectile events nocturnally.

F. Technological Characteristics Summary

The NEVA™ System is substantially equivalent to the RigiScan® Plus System in terms of technology and uses.

Differences that exist between these devices, relating to technical specifications, physical appearance and design, do not affect the relative safety and effectiveness of the NEVA™ System.

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G. Performance Data

Performance testing raised no issues, and the 510(k) included Comparative Testing and Function and Beta Testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Philip A. Messina
President and COO
UroMetrics, Inc.
445 Etna Street, Suite 56
Saint Paul, Minnesota 55106

Re: K980627
UroMetrics NEVA™ System
Dated: February 16, 1998
Received: February 18, 1998
Regulatory Class: Unclassified
Product Code: 78 LIL

Dear Mr. Messina:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number:

Device Name: NEVA™ System

Indications for Use:

- Measure and record penile erectile events nocturnally

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 USE
(optional Form 1-2-96)

Robert P. Rathin
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 980627