K 971142

**510(k) Summary of Safety and Effectiveness**
**Urovations Nerve Stimulator**

OCT 27 1997

## Company Name

Urovations Inc.
64 A Street
Needham, MA 02194

## Official Contact

Frederick Tobia
Director, Clinical and Regulatory Affairs

## Device Name

| | |
|---|---|
| Proprietary Name: | Urovations Nerve Stimulator |
| Common Name: | Nerve Stimulator/Locator |
| Classification Name(s): | 21 CFR § 874.1820 Surgical Nerve Stimulator/Locator |

## Predicate Devices used for Substantial Equivalence

| | |
|---|---|
| Grass Nerve Stimulator | K844216 |
| Brown Nocturnal Penile Tumescence Monitor | K830221 |

## Intended Use

The Urovations Nerve Stimulator is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

## Indications for Use

The Urovations Nerve Stimulator is indicated for use in the stimulation of the cavernosal nerves during open prostatectomy (surgical) procedures, aiding the surgeon in locating these nerves. The device is designed as an adjunct to current open prostatectomy procedures in which a nerve sparing technique is used. The Nerve Stimulator is not designed to replace the surgeon's expertise in mapping out the vascular bundles. Each surgeon's skill determines whether these nerves are spared regardless of any aid.

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## Description

The Urovations Nerve Stimulator is a electrical Nerve Stimulator designed for use during open prostatectomy (surgical) procedures. The stimulator provides a biphasic current pulse with variable amplitude between 1 - 20mA, a constant pulse width of 800μsec/phase, and a constant frequency of 16Hz. The stimulation is applied to the body by the surgeon in order to locate and test the excitability of the cavernosal nerves.

## Summary of Standards Achieved

The Urovations Nerve Stimulator meets UL-544 specifications for electronic medical devices, conforms to AAMI ES1-1993 Safe Current Limits, and meets IEC-601 standards for electronic medical devices.

## Pre-clinical and Clinical Testing

A variety of physical tests were conducted on the Urovations Nerve Stimulator to characterize its physical properties, safety margins, and failure modes, as part of a failure modes and effects analysis. In addition, extensive biocompatibility testing was conducted on the materials which will have human contact to demonstrate that the materials are biocompatible, suitable and safe for their intended use.

A clinical study was conducted to determine if the Urovations Nerve Stimulator provides electrical stimulation to the cavernosal nerves during radical prostatectomy procedures. The results of the study indicate the Urovations Nerve Stimulator provides an electrical charge to stimulate the cavernosal nerves and elicits a visible and measurable response in tumescence. No reported adverse events were associated with device use.

## Summary

In summary, the Urovations Nerve Stimulator is substantially equivalent to legally marketed devices. Furthermore, based on the results of preclinical and clinical testing, the nerve stimulator is substantially equivalent to these devices with respect to its performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1997

Ms. Nancy C. MacDonald
Manager, Clinical & Regulatory Affairs
UroMed Corporation
64 A Street
Needham, Massachusetts 02194

Re: K970971
Urovations Nerve Stimulator
Dated: September 22, 1997
Received: September 23, 1997
Regulatory class: II
21 CFR §874.1820/Product code: 77 ETN
21 CFR §876.4730/Product code: 78 FGM

Dear Ms. MacDonald:

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 (for the indications for use stated in the enclosure) 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

Enclosure

**510(k) Number (if known):** K970971

**Device Name:** Urovations Nerve Stimulator

**Indications for Use:**

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(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 ____
(Per 21 CFR 801.109)

Robert P Rathbun
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970971