DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Debra Reisenthel
President and Chief Executive Officer
Novasys Medical, Inc.
39684 Eureka Drive
Newark, California 94560

JUL 2 2 2005

Re: k042132
Trade/Device Name: Novasys Medical's Transurethral RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Applicator, Transurethral, Radio Frequency, For Stress Urinary Incontinence In Women
Regulatory Class: Class II
Product Code: NVJ
Dated: July 14, 2005
Received: July 14, 2005

Dear Ms. Reisenthel:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K042132

Device Name: Novasys Transurethral RF System

Indications For Use:

**The Novasys Transurethral RF System is indicated for the transurethral treatment of female stress urinary incontinence due to hypermobility in women who have failed conservative treatment and who are not candidates for surgical therapy.**

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

7/22/05



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K042132

# 16 SUMMARY

## 16.1 510(k) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

## 16.2 CONCLUSION

## 16.1 510(k) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Novasys Medical, Inc., is providing a summary of the safety and effectiveness information available for the Novasys Transurethral RF System, as well as the substantial equivalence decision-making process used for the Novasys Transurethral RF System.

### SPONSOR/APPLICANT NAME AND ADDRESS

Novasys Medical, Inc.
39684 Eureka Drive
Newark, CA 94560
(510) 226-4060 (telephone)
(510) 353-0524 (facsimile)

### SPONSOR/APPLICANT CONTACT INFORMATION

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### DATE OF PREPARATION OF 510(k) SUMMARY

August 6, 2004

### DEVICE TRADE OR PROPRIETARY NAME

Novasys Transurethral RF System

### DEVICE COMMON NAME

Electrosurgical System

### DEVICE CLASSIFICATION NAME

Electrosurgical Cutting and Coagulation Device and Accessories (per 21 CFR 878.4400)

## DEVICE PRODUCT CODE

GEI

## DEVICE PANEL

General and Plastic Surgery

## IDENTIFICATION OF THE LEGALLY MARKETED DEVICES AGAINST WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED

### *1. Technological Characteristics Predicate Devices*

- Novasys Electrosurgical Electrode Family
  Novasys Medical, Inc.
  K001150
- Novasys "Ariel" RF Electrosurgical Control Module and Accessories
  Novasys Medical, Inc.
  K013730

### *2. Indication for Use Statement Predicate Device*

- SURx RF System
  SURx, Inc.
  K020952

## DEVICE DESCRIPTION

The Novasys Transurethral RF Generator delivers controlled, low-level radiofrequency energy through the Novasys Transurethral RF Probe for localized collagen denaturation.

## INDICATION FOR USE STATEMENT

The Novasys Transurethral RF System is indicated for the transurethral treatment of female stress urinary incontinence due to hypermobility.

## SUBSTANTIAL EQUIVALENCE

### *1. Technological Characteristics Predicate Devices*

The technological characteristics of the Novasys Transurethral RF System are equivalent to those of the cited predicate electrosurgical devices and are similar to other legally

marketed RF devices distributed by other manufacturers. The predicate devices are equivalent in terms of design, materials, principle of operation, and product specifications. Any differences between the Novasys Transurethral RF System and the predicate devices do not raise new issues regarding safety or effectiveness.

***2. Indication for Use Statement Predicate Device***

Substantial equivalence for the Novasys Transurethral RF System Indication for Use Statement is supported by the cited predicate device with a Indication for Use Statement that is identical in terms of medical disorder (stress urinary incontinence), pathophysiological etiology (hypermobility), and patient population (female). The Indication for Use Statement for the Novasys Transurethral RF System is supported by the results of the clinical trials.

**SUMMARY OF NON-CLINICAL AND PRE-CLINICAL DATA**

Results of bench testing and pre-clinical (animal) studies demonstrated that the Novasys Transurethral RF System met its performance specifications, was technologically substantially equivalent to its predicate devices, and that no new issues of safety or effectiveness were introduced.

**SUMMARY OF CLINICAL DATA**

Results of clinical trials (both the Pilot Clinical Trial and the subsequent U.S. Multicenter Clinical Trial) demonstrated that the Novasys Transurethral RF System functioned as clinically designed and intended. Sufficient data has been gathered from clinical investigations to determine that the Novasys Transurethral RF System performs as clinically designed and intended, and that no new issues of safety or effectiveness were introduced.

**SUBSTANTIAL EQUIVALENCE DECISION-MAKING PROCESS**

The guidance document titled, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices, Substantial Equivalence Decision-making Process (Detailed),"

revised August 1992 by the Center for Devices and Radiological Health, was used to determine the substantial equivalence for the Novasys Transurethral RF System.

## 16.2 CONCLUSION

Stress urinary incontinence (SUI), the most common form of urinary incontinence disorder, affects an estimated 17 million Americans, adversely impacting their quality of life. Numerous and varied therapeutic approaches are currently offered to treat this life-altering disorder, ranging from non-invasive pelvic floor muscle exercises and minimally-invasive pelvic floor muscle electrical stimulation to invasive surgical bladder suspensions and slings.

The overwhelming majority of women suffering from SUI do not select a definitive treatment from the available options. Research has demonstrated that the majority of these women are seeking a treatment which is safe, rapid, non-surgical, associated with minimal recovery requirements, and does not require frequent repeat administration. The treatment effectiveness expected by female SUI patients in return for these treatment characteristics is improvement in their quality of life.

The least invasive currently available SUI treatment options suffer from issues relating to treatment efficacy, durability, chronicity, and patient compliance. The more invasive SUI treatment modalities are plagued by concerns regarding treatment safety and burdensome recovery requirements.

*This submission presents evidence that the Novasys Transurethral RF System fulfills the wishes and expectations of women suffering from this disorder.* As desired by patients, the Novasys Transurethral RF System treatment has demonstrated safety, with no Serious Adverse Events and only limited Anticipated Adverse Events occurring during the 12 month U.S. Clinical Trial. The non-surgical, outpatient procedure is rapidly performed without the need for general anesthesia and is associated with minimal recovery requirements. Patients have demonstrated improvement in quality of life, reduction in

number of daily incontinence episodes, reduction in daily incontinence pad use, and improvement in Valsalva leak point pressure 12 months following treatment.

Along with the demonstration of Novasys Transurethral RF System safety and effectiveness, this submission has presented evidence of substantial equivalence to legally marketed predicate devices for both technological characteristics and Indication for Use Statement.