Ms. Debra Reisenfeld
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 888.4400
Regulation Name: Applicator, Transurethral, Radio Frequency, For Stress Urinary Incontinence In Women
Regulatory Class: Class II
Product Code: NV1
Dated: July 14, 2005
Received: July 14, 2005

Dear Ms. Reisenfeld:

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 531-541 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 Tuilman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
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)

Concurrence of CDRH, Office of Device Evaluation (ODF)

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16 SUMMARY

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

16.2 CONCLUSION
15.1 510(k) SUMMARY (AS REQUIRED BY 21 CFR 807.92)

Pursuant to Section 12. Part (a)(3)(A) 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
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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
Electrourgical 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.
     K01150
   - Novasys "Ariel" RF Electrosurgical Control Module and Accessories
     Novasys Medical, Inc.
     K013736

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

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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),"
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 improved 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 Novasyt Transurethral RF System fulfills the wishes and expectations of women suffering from this disorder. As desired by patients, the Novasyt 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.