DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2000

Thomas C. Wehman, Ph.D.
Regulatory Affairs
Novasys Medical, Inc.
687 North Pastoria Avenue
Sunnyvale, California 94086

Re: K001151
Trade Name: Novasys Medical, Inc.
Electrosurgical Electrode Family
(Model 200 - Sponge Catheter Two Needle Electrode with Irrigation and Suction,
Model 400 - Sponge Catheter Four Needle Electrode with Irrigation and Suction, and
Model 401 - Sponge Catheter Four Needle Staggered Electrode with Irrigation and Suction)
Regulatory Class: II
Product Code: GEI
Dated: April 3, 2000
Received: April 10, 2000

Dear Dr. Wehman:

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) 594-4595. 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,

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

9.3

Indications For Use

510(k) Number (if known): K001151

Device Name: Novasys Medical, Inc.
Electrosurgical Electrode Family

Model 200 – Sponge Catheter Two Needle Electrode with Irrigation and Suction
Model 400 – Sponge Catheter Four Needle Electrode with Irrigation and Suction
Model 401 – Sponge Catheter Four Needle Staggered Electrode with Irrigation and Suction

Indications for Use: Indicated for coagulation of tissue

These devices are intended for use by qualified medical personnel trained in the use of electrosurgery.

To be used exclusively with the Curon Medical Stretta Control Module radiofrequency generator (510(k) K991529)

Contraindications: The use of electrosurgery is contraindicated when, in the judgement of the physician, electrosurgical procedures would be contrary to the best interest of the patient.

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

Concurrence of CDRD, Office of Device Evaluation (ODE)

Prescription use ✓
(per 21 CFR 801.109)

OR

Over-the Counter Use____
(Optional format 1-2-96)

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001151