K991529

SEP 14 1999

SECTION 8 PREMARKET NOTIFICATION 510(k) SUMMARY, TRUTHFUL AND ACCURATE STATEMENT, INDICATIONS FOR USE

8.1 Premarket Notification 510(k) Summary

510(k) Summary of Safety and Effectiveness
Conway Stuart Medical, Inc.
Stretta Control Module Model S400 RF Generator and Accessories

Intended Use:

The Conway Stuart Medical Stretta Control Module Model S400 RF generator, in combination with Conway Stuart Medical electrodes, is indicated for coagulation of tissue. This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Submitted by:

Conway Stuart Medical, Inc.
735 Palomar Avenue
Sunnyvale, CA 94086
Phone: (408)733-9910
Fax: (408)522-8699

Contact Person:

Thomas C Wehman, Ph.D.
Regulatory Affairs
Phone: (408) 733-9910

Date Summary Prepared:

April 27, 1999

Name of Device:

Proprietary Name: Stretta Control Module Model S400 RF Generator and Accessories

Common/Usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical Device (per 21CFR§878.4400)

Predicate Device:

Conway Stuart Medical Model C4

Description:

The Stretta Control Module Model S400 is an electrosurgical generator that is designed to deliver controlled low level radiofrequency energy for localized tissue coagulation. The Stretta generator has controls for maximum temperature, power delivered, energy delivered and time of energy delivered. The unit has readout for total energy delivered, impedance, maximum power and temperature for up to six channels. Connectors located on the front panel include electrode connectors and a foot pedal. A fluid pump is integrated into the Stretta generator to deliver cooling fluid to the surrounding tissue adjacent to the electrode.

System accessories include an AC power cord, a single-pedal footswitch and a connecting cable.

Comparison to Predicate Device:

The Stretta Control Module Model S400 electrosurgical generator and accessories has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance validation testing has been done to validate the performance of this device. The comparison and validation results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

Thomas C. Wehman, Ph.D.
Regulatory Affairs/Quality Assurance
Conway Stuart Medical, Inc.
735 Palomar Avenue
Sunnyvale, California 94086

Re: K991529
Trade Name: Stretta Control Module Model S400 Radiofrequency Electrosurgical Generator with Pump
Regulatory Class: II
Product Code: GEI
Dated: July 30, 1999
Received: August 2, 1999

Dear Dr.Wehman :

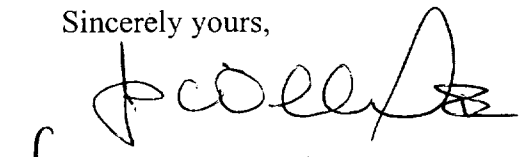
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.3 Indications for Use

510(k) Number: K991529

Device Name: Conway Stuart Medical Stretta Control Module Model S400 Radiofrequency Electrosurgical Generator with Pump

Indications for Use: The Stretta Control Module Model S400 RF electrosurgical generator with pump, in combination with CSM electrodes, is indicated for coagulation of tissue. This device is intended for use by qualified medical personnel, trained in the use of electrosurgery.

Contraindications for Use: The use of the Stretta Control Module Model S400 RF electrosurgical generator with pump is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the patient's best interest.

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 21CFR§801.109) (Optional format 1-2-06)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991529