K014216 1/3

Attachment 14

MAR 2 1 2002

510(k) SUMMARY

Curon Medical, Inc.'s
Secca™ System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter:

Curon Medical, Inc.
735 Palomar Avenue
Sunnyvale, CA 94085
408-733-9910 main
408-522-8699 fax

Contact Person:

Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson, LLP
555 13th Street, N.W.
Washington, DC 20004
Phone: (202) 637-5794
Fax: (202) 637-5910

Date Prepared: December 20, 2001

Name of Device

Secca™ System

Common or Usual Name

Radiofrequency electrosurgical generator and electrosurgical accessories

Classification Name

Electrosurgical cutting and coagulation device and accessories

Predicate Devices

1. Stretta System (K010210
2. Stretta System (K000245)
3. Stretta Inflatable Basket Electrode (K991291)
4. Secca Tubular Electrode (K000170)

5. A4000 Tubular Electrode (K992542)
6. BioCare International's BCI-100 Fecal Incontinence System (K904646)
7. Biosearch, Inc.'s Anorectal Biofeedback System 5 (K913736)
8. Ethicon's PowerStar Bipolar Scissors (K981361)
9. Ellman's Surgitron Radiolase System and Accessories (K992382)
10. Portlyn Corporation's Dynabite Hot Gastroenterology Biopsy Forceps (K970083)

Intended Use

The Secca™ System is intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.

Substantial Equivalence

The Secca System is substantially equivalent to other marketed devices that have received premarket clearance. The general intended use of the Secca System to coagulate tissue electrosurgically is the same as the general intended use of Curon Medical's previously cleared Stretta System (K010210 and K000245) ("Stretta"), Secca Tubular Electrode (K000170), A4000 Tubular Electrode (K992542), and Stretta Inflatable Basket Electrode (K991291). The Secca System's specific indication for use for treatment of fecal incontinence is also substantially the same as for a number of predicate biofeedback devices. Specifically, BioCare International's BCI-100 Fecal Incontinence System (K904646) ("BCI-100 System") and Biosearch, Inc.'s Anorectal Biofeedback System 5 (K913736) ("Anorectal System 5") are cleared for biofeedback training of the anal sphincter in the treatment of fecal incontinence and/or constipation. Finally, FDA also has cleared a number of other devices for use in anorectal procedures to perform tissue ablation or coagulation, including Ethicon's PowerStar Bipolar Scissors (K981361) device, Ellman's Surgitron Radiolase System and Accessories (K992382), and Portlyn Corporation's Dynabite Hot Gastroenterology Biopsy Forceps (K970083) device. Although these devices are not specifically indicated for use in the treatment of fecal incontinence, like the Secca System they are all generally used to apply electrical energy within the lower GI tract for treatment of gastroenterological pathologies.

Comparing the principles of operation and the technological characteristics of the Secca System to its predicates, the device and generator design also is substantially similar to the Company's previously cleared Stretta System (K010210 and K000245), except for a few minor modifications. Likewise, its design is substantially similar to Curon's cleared Tubular Electrodes (K000170 and K992542) and Stretta Inflatable Basket Electrode (K991291). All of these devices have been designed, tested, and produced by the same manufacturer in much the same manner.

Any minor differences in indications between the Secca System and the predicates do not alter its therapeutic effect, considering the impact on safety and effectiveness, as confirmed by preclinical and clinical testing. Furthermore, although minor modifications have been made to the technological features of the Secca System since the Company's clearance of the predicate Stretta System, these changes are minimal and do not affect the safety or effectiveness of the Secca System. Thus, the Secca System presents no new significant technological features compared to the previously cleared predicates. Therefore, because the intended use and indications for use of the device are substantially the same as the cleared predicates and there are no significant new technological features, the device may be found substantially equivalent to those other devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2002

Curon Medical, Inc.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K014216
Trade Name: Secca System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 20, 2001
Received: December 21, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

K014216

SECCA™ SYSTEM INDICATIONS FOR USE:

The Secca™ System is intended for general use in the electrosurgical coagulation of tissue and intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014216