SEP 2 6 2003

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.92

Submitter:

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Date Summary Prepared: June 27th, 2003

Product Identification

Proprietary Name: Celon *ENT* System

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

Common Name: Electrosurgical Device and Accessories

Manufacturer:

Celon AG medical instrument
Rheinstrasse 8
14513 Teltow
Germany

Distributor: pending

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Legally Marketed Device:

The Celon *ENT* System is of comparable type and is substantially equivalent to the following currently marketed devices:

Device	510(k) Number	Date Cleared
ArthroCare AccENT Electrosurgery System	K973478	January 9th, 1998
ArthroCare ENTec Reflex Wand Electrodes	K000036	February 4th, 2000
ArthroCare ENTec Reflex Wand Electrodes	K000778	May 3rd, 2000
Somnus Somnoplasty System	K971450	July 17th, 1997
Somnus Somnoplasty System	K973618	December 19th, 1997

It complies with the same or equivalent standards and has the same intended use.

Device Description

The Celon *ENT* System is comprised of a power control unit (CelonLab *ENT*) and bipolar coagulation electrodes. The CelonLab *ENT* power control unit delivers a bipolar output via the bipolar coagulation electrodes of type CelonPro*Breath*, CelonPro*Sleep*, and CelonPro*Sleep* PLUS. A neutral electrode (return conductor) is not required. The power control unit is user-friendly with a user display showing all the necessary process parameters. After switching on the equipment, the user selects the level of power and activates the radio frequency (RF) current by depressing the foot switch. The power control unit delivers an acoustic signal as an indicator of the coagulation status. Usually, general electrosurgical units have a fixed activation tone. However, in the case of the CelonLab *ENT* power control unit, the frequency of the acoustic signal is proportional to the tissue impedance. This permits acoustic monitoring of the coagulation status by the operator, since the latter is directly correlated with the impedance. If the impedance increases above a certain limit, signifying that the coagulation process is complete, this is additionally indicated by a clock pulsed sound and the power output is ceased automatically. Overdose effects in the treated tissue area are excluded by this power control function. The procedure time will be set automatically by the power control unit. The time interval between activation of the power control unit and the end of the coagulation procedure depends on applicator type, tissue properties and power setting, and can vary between 3 seconds and several minutes.

Accessories included with the power control unit include a line power cable and single pedal foot pedal (CelonFoot*Switch*).

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Materials: Materials and construction of the Celon *ENT* System are compliant with the international electrical safety standards IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, and the American national standard ANSI/AAMI HF-18. Additionally, the materials used in the design and construction of the CelonPro*Breath*, CelonPro*Sleep*, and CelonPro*Sleep* PLUS bipolar coagulation electrodes, which have direct contact with the patient, are biocompatible according to ISO 10993 or USP 23 Class VI.

Design: The system is designed to be a bipolar electrosurgical coagulation device with an automatic power control, including automatic output power reduction and acoustic monitoring of coagulation status.

Intended Use of the Device

This Celon *ENT* System has the same intended use as the legally marketed devices. This application system, comprising the CelonLab *ENT* power control unit and the CelonPro*Breath*, CelonPro*Sleep*, and CelonPro*Sleep* PLUS bipolar coagulation electrodes, is indicated for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery including:

CelonPro*Breath*:	Submucosal tissue shrinkage for nasal airway obstruction by reduction of hypertrophic nasal turbinates
CelonPro*Sleep*:	Submucosal tissue shrinkage and tissue coagulation in the uvula/soft palate for the treatment of snoring
CelonPro*Sleep* PLUS:	Submucosal tissue shrinkage and tissue coagulation in the uvula/soft palate for the treatment of snoring

The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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Comparison with Legally Marketed Device:

It is the opinion of Celon AG medical instruments that the Celon *ENT* System is of a type and substantially equivalent to legally marketed devices with respect to intended use and technological characteristics. It will comply with the safety requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, ANSI/AAMI HF-18 and applicable collateral and particular standards. Furthermore, the CelonPro*Breath,* CelonPro*Sleep*, and CelonPro*Sleep* PLUS bipolar coagulation electrodes, which have direct contact with the patient, are biocompatible according to ISO 10993 or USP 23 Class VI. In addition, performance validation testing has been done to validate the performance of the device. The comparison results presented in this 510(k) notification show that the device is substantially equivalent to legally marketed devices and is safe and effective in its intended use.

Conclusions

The Celon *ENT* System does not result in any new potential safety risks and performs as well as or better than devices legally on the market. Celon AG medical instruments consider the Celon *ENT* System to be equivalent to other marketed devices with the same indications for use and meeting similar standards.

Legal Notice

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2003

Celon AG Medical Instruments
c/o Ms. Pamela Gwynn
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K032838
Trade/Device Name: Celon ENT System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 18, 2003
Received: September 11, 2003

Dear Ms. Gwynn:

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 (301) 594-4659. 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/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

6 Statement of Intended Use

510(k) Number: ~~pending~~ K032838

Device Name: Celon *ENT* System

Indications For Use:

This application system, comprising the CelonLab *ENT* power control unit and the CelonPro*Breath*, CelonPro*Sleep*, and CelonPro*Sleep* PLUS bipolar coagulation electrodes, is indicated for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery including:

CelonPro*Breath*:	Submucosal tissue shrinkage for nasal airway obstruction by reduction of hypertrophic nasal turbinates
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CelonPro*Sleep* PLUS:	Submucosal tissue shrinkage and tissue coagulation in the uvula/soft palate for the treatment of snoring

The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) Miriam C. Provost

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

510(k) Number K032838