Section 5: 510(K) Summary of Safety & Effectiveness

K100543

Submitted By	MEDISISS 2747 SW 6th St. Redmond, OR 97756
Contact Names	Brandi James Sr. Director Quality Assurance/Regulatory Affairs P: 541-923-3310 F: 541-923-3375 E: bjames@MEDISISS.com
Date Prepared	February 22, 2010
Proprietary Device Name	MEDISISS Reprocessed ENT Ablation Wands (Coblators)
Classification	Electrosurgical Electrodes, Class II, Electrosurgical cutting and coagulation device and accessories, General and plastic surgery (21 CFR 878.4400), GEI
Predicate Devices	K070374 ArthroCare ENT® Plasma Wands™ K014290 ArthroCare ENTec® Plasma Wands™ K063538 ArthroCare ENT® Plasma Wands™ K013463 ArthroCare ArthroWands®, ENTec® EVac™ Plasma Wand™ K012669 MEDISISS Reprocessed Soft Tissue Ablators
Intended Use	MEDISISS Reprocessed ENT Ablation Wands (Coblators) are indicated for coagulation, ablation, resection, of soft tissue and hemostasis of blood vessels in otoloaryngology (ENT) procedures including: tonsillectomy/adenoidectomy and soft tissue reduction.
Device Description	The device is a high frequency, bipolar ablation wand with suction capability that contains an integrated electrical cable and integrated saline delivery system.
Substantial Equivalence	The indications for use, technological characteristics, and performance specifications are substantially equivalent to the predicate devices.

JUL 23 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MEDISISS
% Ms. Brandi J. James
Sr. Director, Quality Assurance/
Regulatory Affairs
2747 SW 6th Street
Redmond, Oregon 97756

JUL 23 2010

Re: K100543
Trade/Device Name: Medisiss Reprocessed ENT Ablation Wands
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 22, 2010
Received: February 25, 2010

Dear Ms. James:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number: TBD

Device Name: MEDISISS Reprocessed ENT Ablation Wands (Coblators)

Indications For Use:

MEDISISS Reprocessed ENT Ablation Wands (Coblators) are indicated for coagulation, ablation, resection, of soft tissue and hemostasis of blood vessels in otoloaryngology (ENT) procedures including: tonsillectomy/adenoidectomy and soft tissue reduction.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100543

Page 1 of ____