APR 2 8 2014

510(k) Summary

As Required By 21 CFR 807.92

Date of Summary Preparation	April 25, 2014
Submitter and Owner's Name and Address	Halt Medical, Inc. 131 Sand Creek Road, Suite B Brentwood, CA 94513 Main: (925) 634-7943 Fax: (925) 634-7841
Contact Person	Clarisa A. Tate VP Director of RA & QA, Halt Medical, Inc. Office: (925) 271-0626 e-mail: ctate@haltmedical.com
Trade Name	Acessa Guidance Handpiece
Common Name	Acessa Guidance Handpiece
Classification Name	Unipolar endoscopic coagulator-cutter and accessories
Classification	Class II
Product Code	HFG
Classification Panel	Obstetrics and Gynecology
Classification Regulation	21 CFR §884.4160
Legally Marketed Device to which substantial equivalence is claimed	Acessa System (K121858)
Intended Use	The Acessa Guidance Handpiece is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.
Device Description	Acessa Guidance Handpiece (Model Number 5300): The Acessa Guidance Handpiece, when used with the tracking system, is meant to guide the tip of the Handpiece up to the uterine serosa. Once the device is advanced into the uterus, standard ultrasound views are used to guide the tip to the fibroid. Ultrasound visualization for fibroid penetration and treatment remain unchanged. The Acessa Guidance Handpiece is a single-use only, sterile, radiofrequency (RF) applicator that connects to the Acessa Generator by a custom Cable. The Handpiece consists of a handle with a trocar shaft, active needle tip, and seven deployable needle electrodes each with embedded thermocouple sensors for real-time temperature feedback. The Acessa Guidance Handpiece also has control buttons that allow the user to access the User Interface. This Acessa Guidance Handpiece also contains the magnetic guidance sensor used to determine spatial location. The embedded sensor and SROM can be used with the electromagnetic tracking technologies to track the positions of an Ultrasound Transducer and the Handpiece shaft, and draws virtual representations of them in their spatial relationship, so that a physician can predict the Handpiece shaft's future path in relation to the features in the ultrasound slice. These electromagnetic tracking technologies are considered optional accessories to procedures where ultrasound is currently used for visualization, such as the

	Acessa System procedure.
Technological Characteristics Compared to Predicate Devices	The design features and principal modes of operation of the Acessa Guidance Handpiece is the equivalent to the commercially available Acessa System. It is the same product with the exception of the addition of the embedded sensor and SROM so that the device may also be used, if desired, with electromagnetic tracking technologies that can draw a virtual representation of the device. Application of radiofrequency energy with both devices within a surgical procedure is completed in the same manner. Substantial equivalence is established with respect to the same indication for use, principal design, type of energy used or delivered, performance and safety requirements. Treatment using the Acessa Guidance Handpiece is the same as that of how the predicate would be used.
Performance Testing	The Acessa Guidance Handpiece was subjected to electrical and safety testing according to risks assessments performed based on the differences with the predicate device. EMC and safety testing were completed on the device as required within EN/IEC 60601-1:2005/2006 3rd edition Medical Electrical Equipment Part 1 General Requirements for Safety, EN/IEC 60601-1-2:2007 3rd edition Medical Electrical Equipment General Requirements for Basic Safety and Essential Performance Collateral Standard Electromagnetic Compatibility Requirements and Tests , EN/IEC 60601-2-2:2009 5th edition Medical Electrical Equipment Particular Requirements for the Safety of High Frequency Surgical Equipment. The device passed all testing. A series of biocompatibility testing also demonstrated that the device with its additional materials are safe, suitable, and appropriate for their intended use and in compliance with ISO 10993-1:2009 4th edition Biological Evaluation of Medical Devices Part 1 Evaluation and Testing within a Risk Management Process, ISO 10993-5:2009 3rd edition Biological Evaluation of Medical Devices Tests for In Vitro Cytotoxicity, ISO 10993-10:2010 2nd edition Biological Evaluation of Medical Devices Tests for Irritation and Delayed-Type Hypersensitivity, and ISO 10993-11:2006 2nd edition Biological Evaluation of Medical Devices Tests for Systemic Toxicity. The Acessa Guidance Handpiece was also subjected to flexural strength testing as well as compatibility testing with an electromagnetic tracking system. The device met all the criteria.
Conclusion	The Acessa Guidance Handpiece is substantially equivalent to the legally marketed medical device as demonstrated by the technological characteristics comparison and performance testing completed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 28, 2014

Halt Medical, Inc.
Clarisa Tate
VP of Regulatory Affairs & Quality Assurance
131 Sand Creek Road, Suite B
Brentwood, CA 94513

Re: K132184
Trade/Device Name: Acessa System
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HFG
Dated: April 4, 2014
Received: April 7, 2014

Dear Clarisa Tate,

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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K132184

Device Name: Acessa System

Indications for Use: The Acessa System is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

The Acessa System consists of the following components:

- Generator (Model Number 1000)
- Handpiece (Model Number 2000 or 5300)
- Handpiece Cable (Model Number 4200)
- Pads (Model Number 3000)
- Pad Cable (Model Number 4300)
- Power Cord (Model Number 4110)
- Foot Pedal (Model Number 4100)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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