510(k) Summary

NOV 5 2012

As Required By 21 CFR 807.92

Date of Summary Preparation	November 2, 2012
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 Senior Director of RA & QA, Halt Medical, Inc. Office: (925) 271-0626 e-mail: ctate@haltmedical.com
Trade Name	The Acessa System
Common Name	The Acessa System
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	Halt 2000GI™ Electrosurgical Radiofrequency Ablation System (K094009)
Intended 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.
Device Description	The Acessa System includes the following system components: • Generator (Model Number 1000): Provides RF energy to the Handpiece through the Handpiece Cable. • Handpiece (Model Number 2000): Consisting of a disposable handle with a trocar-pointed shaft and 7 deployable needle electrodes. For use only disposable electrosurgical devices provided by Halt Medical, Inc. • Handpiece Cable (Model Number 4200): Connects Handpiece to the Generator. This extension cable is provided with the Generator. • Pads (Model Number 3000): A disposable set of 2 units, providing the return path for the RF energy applied by the Handpiece. Use only the Pads provided by Halt Medical, Inc. • Pad Cable (Model Number 4300): Connects the Pads to the Generator. This extension cable is provided with the RF Generator. • Power Cord (Model Number 4110): A medical grade power cord that provides AC power to the Generator. The Power cord is provided with the Generator. • Foot Pedal (Model Number 4100): Pneumatic foot pedal with tubing used to turn RF energy on and off. The Foot Pedal with tubing is provided with the Generator.

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	The Acessa System is designed to deliver up to 200 W of RF power at 460 kHz in three operational modes: Temperature Control, Manual Control and Coagulation Mode. A touch screen with a graphical user interface (GUI) enables selection of operational parameters such as the mode of operation, the ablation time, the target temperature, and the power delivery level. With the Handpiece placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the Generator. If the measured parameters are outside the acceptable limits, the RF energy delivery automatically stops and a message appears on the graphical user interface. RF energy during an ablation or coagulation can also be stopped at any time by the user by pressing the foot pedal. NOTE: The Acessa System must be used under laparoscopic ultrasound guidance. Laparoscopic ultrasound equipment is not included with the Acessa System.
Intended Use and Technological Characteristics Compared to Predicate Devices	The Acessa System and the Halt 2000GI System do not have the same Indications for Use statement, as the Acessa System includes the specific indication of "treatment of symptomatic uterine fibroids." The difference between the Indications for Use statements of the Acessa System and Halt 2000GI System does not alter the intended therapeutic effect of the device. Like the Halt 2000GI System, the Acessa System uses coagulation or ablation of soft tissue to achieve its therapeutic effect, (i.e., treatment of symptomatic uterine fibroids). The technological characteristics of the Acessa System are equivalent to commercially available Halt 2000GI™ System. It is the same product.
Performance Testing	The Acessa System was subjected to a battery of electrical, mechanical, and software validation testing, as well as applicable safety requirements (EN/IEC 60601-1, EN/IEC 60601-1-2, EN/IEC 60601-2-2). The system passed all testing. • EMC and safety testing were completed on the device as a whole and per component as required within EN/IEC 60601-1, EN/IEC 60601-1-2, EN/IEC 60601-2-2. • A series of tests were performed to qualify and quantify the mechanical and functional properties of the device including shelf-life or service life testing. Ablation output and safety features were evaluated for the Generator and its accessories. Retention forces and ultrasound visibility was evaluated for the Handpiece. Fluid adherence, separation, and pull tests were completed to evaluate the Pads. • The software and hardware for the Generator has been developed, verified and validated to evaluate the graphical user interface (GUI), alerts, communication between components, real-time feedback to the user via the device's sensors, power control, and software/hardware interface. • A full system verification was completed to ensure safety is met in all related areas required by internal specifications, guidance documents, and standards.

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A series of biocompatibility testing also demonstrated that the device materials are safe, suitable, and appropriate for their intended use and in compliance with ISO 10993-1, ISO 10993-5, and ISO 10993-10.

Animal and bench ablation testing also successfully demonstrates that the Acessa System performs as intended and per specifications. The ablation capability was confirmed and the radiofrequency ablation provides a reproducible, discretely demarcated zone of tissue necrosis which was surrounded by normal tissue perfused with blood.

The Acessa System has undergone an IDE clinical trial under G080163 with identifier NCT00874029 under clinicaltrials.gov.

Clinical trials results demonstrated that radiofrequency volumetric ablation with the Acessa System effectively reduced the amount of menstrual blood loss, decreased the severity of fibroid symptoms, and improved health-related quality of life for up to 12 and 24 months post-treatment. The results also demonstrated the Acessa System's safety profile is acceptable with a high benefits to low risk ratio. Treatment with this device provides an outpatient minimally invasive option that allows rapid recovery and that avoids the risks, costs, and discomfort of major surgery.

- Peri-hysterectomy feasibility study was conducted to evaluate the device for acute procedural and device safety. Various fibroid locations and types were encountered during this study. Pathology reports of the ablation zones were correlated per patient, per fibroid, with procedure documentation. From these data, it is shown that the ex vivo bench testing ablation results are predictive of the ablations in fibroid tissue in-vivo. There were no device-related adverse events in this study.
- Prospective, non-randomized, longitudinal Phase II studies using the Acessa System were conducted at two separate centers to establish early safety and effectiveness data. Various fibroid types and locations were treated in this study. The patients were followed to 12 months using validated questionnaire for fibroid symptoms (UFS-QOL) as well as menstrual pad counts. The mean uterine volume at baseline was 204.4 cm3. At 6 months and 12 months post-treatment, the mean uterine volume was significantly reduced to 155.0 cm3 ($p= 0.012$) and 151.4 cm3 ($p = 0.009$), respectively. The percent of subjects demonstrating reduced uterine volume in contrast to baseline was 82.2%, 80.0%, and 79.3% at the 3-, 6-, and 12-month visits, respectively. At baseline, 77% of subjects reported heavy to very heavy bleeding prior to the treatment. After 12 months post-treatment, 3.5% ($p<0.0001$) reported heavy to very heavy bleeding based on the patient reported survey. The UFS-QOL questionnaire was administered at baseline and at all follow-up visits. The mean percent improvement in Symptom Severity Scores from baseline to post-treatment was 59.6% at 3 months, 65.0% at 6 months, and 79.0%, at 12 months. The mean percent change in HRQL Scores

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from baseline to 3 months post-procedure was 41.6%, from baseline to 6 months post-procedure was 39.7%, and from baseline to 12 months post-procedure was 42.9%. Overall, sixty-five subjects (94.2%) reported improved Symptom Severity Scores and sixty-one subjects (88.4%) reported improved HRQL Scores. In terms of safety, there was only one (1.4%) serious adverse event (i.e., abdominal wall hematoma), which was determined to be related to the procedure. It was treated by laparotomy and vessel ligation.

- The device pivotal (Phase III) study included the treatment of 137 women with symptomatic fibroids including menorrhagia. A total of 11 centers in the United States (9 centers) and Latin America (2 centers) and 13 investigators participated in the study. The primary objectives of the study were to confirm the safety and efficacy of the device for the treatment of symptomatic uterine fibroids. The secondary objectives of the study were to evaluate the change in uterine and fibroid volume, symptom severity, health related quality of life, general health status, and subject satisfaction at 12 months post treatment compared to baseline. UFS-QOL and EQ-5D questionnaire are followed-up to 3 years post-treatment.
    - Various fibroid types and locations were treated in this study totaling 674. The mean number of fibroids treated in the study is 5 per patient (median of 4) with the maximum at 29.
    - There are less than 4% device-related adverse events in the study. Of the 10 (7%) reported serious adverse events, only the pelvic abscess and the serosal colon injury were considered to be related to the device.
    - The mean reduction in menstrual blood flow at 12 months post treatment was 103.6 ml, with 83.9% of subjects experiencing a reduction in blood loss while 15.3% experiencing an increase in bleeding at 12 months post-treatment. When including the subjects lost to follow up as treatment failures, 40.2% (95% CI 31.6% - 48.7%) met the protocol criterion for bleeding relief (defined as ≥50% reduction in menstrual bleeding at 12 months post-treatment) though this did not meet the prespecified study hypothesis that the lower bound of the 95% CI would be ≥45%.
    - Within 24 months, a total of 6 subjects (6/107) have undergone surgical reintervention for fibroid-related bleeding for a cumulative reintervention rate of <6%. Complete 24-month outcomes data on reintervention will be available after March 2013.
    - RFA treatment resulted in a reduction from baseline in total uterine and fibroid volume, as assessed by pretreatment and post treatment contrast-enhanced MRI, at 3 and 12 months post treatment. At 12 months post treatment, the mean reduction in uterine volume was 25.1% and the mean reduction in fibroid volume was 44.3%.
    - Subjects showed a steady improvement in mean Health-Related

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	Quality of Life (HRQL) scores (from a low 37 at baseline to 80 after 24 months post-treatment) and a continuous decrease in Symptom Severity Scores (SSS) scores (from a high 61 at baseline to a low 24 at 24 months post-treatment). o Subjects reported a decrease in disease burden and improved health state with mean EQ-5D scores starting at 71 at baseline and rising to 85 after 24 months. o The results of the OTE surveys showed that 94% of the subjects responded that they were very satisfied, moderately satisfied, or somewhat satisfied with the treatment. At 12-months post treatment, 98% of the subjects reported that they would probably or definitely recommend the procedure to their friends with the same health problem. When asked about effectiveness of the treatment, at least 94% of the subjects responded that the treatment had been somewhat, moderately, and very effective in eliminating their symptoms. o A total of 88 subjects reported that they were working. Subjects returned to work in a median of 5 days and all subjects reported that they returned to normal in a median of 9 days. Ninety-six percent of the subjects in the Halt study were treated on an outpatient basis. o Seven subjects (5.1%) had one or more calcified fibroids that were treated during the RF ablation procedure. Calcified fibroids did not appear to impact the physician's ability to insert the tip of the Handpiece but the data are minimal regarding calcified fibroids at this time.
Conclusion	The Acessa System is substantially equivalent to its proposed predicate 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 20993-002

Letter Date: November 5, 2012

Halt Medical, Inc.
℅ Ms. Clarisa Tate
Senior Director Regulatory Affairs and Quality Assurance
131 Sand Creek Road, Suite B
BRENTWOOD CA 94513

Re: K121858
Trade/Device Name: The Acessa System
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HFG
Dated: October 8, 2012
Received: October 24, 2012

Dear Ms. 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.

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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

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

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Indications for Use

510(k) Number (if known): K121858

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)
- 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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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