K132744
MAY 27 2014

Acessa guidance

Section 5 – 510(k) Summary

As Required By 21 CFR 807.92

Date of Summary Preparation	May 22, 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 of RA & QA, Halt Medical, Inc. Office: (925) 271-0626 e-mail: ctate@haltmedical.com
Trade Name	Acessa Guidance System
Common Name	Acessa Guidance System or electromagnetic tracking system
Classification Name	Unipolar endoscopic coagulator cutter and accessories
Classification	Class II
Product Code	HFG, OEW, IYO
Classification Panel	Obstetrics and Gynecology
Classification Regulation	21 CFR §884.4160
Legally Marketed Device to which substantial equivalence is claimed	AIM System (K121479)
Intended Use	The Acessa Guidance System is indicated for enhancing the ultrasonic image of the Acessa Handpiece and for predicting its future path on a computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended as an optional accessory for use during the Acessa System procedure.
Device Description	The Acessa Guidance System consists of the following components: • Guidance Controller (Model Number 5100): Contains the tracking system and software used to run the system, with attached 4.5m Field Generator cable. • Guidance Ultrasound Transducer Sleeve (Model Number 5500): A disposable sleeve that houses the ultrasound transducer, the magnetic guidance sensor and guidance display control buttons. • Guidance Field Generator (Model Number 5200): The TTFG (Table Top Field Generator) generates a magnetic field that is picked up by the magnetic guidance sensors in the Handpiece and the Ultrasound Transducer Sleeve. • Guidance Handpiece Cable (Model Number 5400): Connects a Guidance Handpiece to the Acessa Generator and the Guidance Controller. • Power Cord (Model Number 4110): A medical grade power cord that provides AC power to the Controller. NOTES:

	• The Acessa Guidance System must be used with laparoscopic ultrasound. Laparoscopic ultrasound equipment is not included with the Acessa Guidance System. • The Acessa Guidance System may only be used with the Acessa System, a radiofrequency ablation device. The Acessa Guidance System uses electromagnetic tracking technology to track the positions of the Guidance Ultrasound Transducer Sleeve and the Guidance Handpiece shaft and draws virtual representations of them in their spatial relationship, so that a physician can predict the Guidance Handpiece shaft's future path in relation to the features in the ultrasound slice. The Acessa Guidance System is considered an optional accessory 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 System is the equivalent to the commercially available AIM System. Both products are configured the same and the software is made by the predicate device's company which they based on their cleared device. Application of electromagnetic tracking technology 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, software used, performance, and safety requirements.
Performance Testing	The Acessa Guidance System 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 by ANSI/AAMI ES 60601-1:2005 with A2:2010 3rd edition Medical Device 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, IEC 60601-1-4:2000 1st edition Medical Electrical Equipment Par 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems. 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 System was also subjected to Guidance Sleeve end cap tensile testing as well as system worse-case accuracy comparison testing in a

	simulated clinical environment. The device met all criteria. Software validations were also conducted, which was conducted by the same manufacturer of the predicate device.
Conclusion	The Acessa Guidance System 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

May 27, 2014

Halt Medical, Inc.
Clarisa A. Tate
Vice President of Regulatory Affairs & Quality Assurance
131 Sand Creek Road, Suite B
Brentwood, CA 94513-2040

Re: K132744
Trade/Device Name: Acessa Guidance System
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar endoscopic coagulator cutter and accessories
Regulatory Class: II
Product Code: HFG
Dated: April 25, 2014
Received: April 28, 2014

Dear Clarisa A. 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,

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):

Device Name: Acessa Guidance System

Indications for Use: The Acessa Guidance System is indicated for enhancing the ultrasonic image of the Acessa Handpiece and for predicting its future path on a computer monitor screen which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended as an optional accessory for use during the Acessa System procedure.

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)

Benjamin R. Fisher -S
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