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

June 27, 2016

Omnitech Systems, Inc.
Jon Barrett
President
450 South Campbell St., Suite #2
Valparaiso, IN 46385

Re: K151976
Trade/Device Name: Omnitech HF Resection Electrodes
Omnitech HF Vaporization Electrode
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: FAS
Dated: December 18, 2015
Received: May 25, 2016

Dear Jon Barrett,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151976

Device Name
Omnitech HF Resection Electrodes
Omnitech HF Vaporization Electrode

Indications for Use *(Describe)*

INDICATIONS FOR USE RESECTION ELECTRODES:

The Omnitech HF Resection electrodes are a bipolar instrument series designed and intended for use in endoscopic urological surgical procedures involving the resection, ablation, or removal of soft tissue and where hemostasis is required. The specific urological indications include use in the prostate, bladder and bladder neck. The procedures for which the devices can be used are: Transurethral resection in saline (TURis), Transurethral prostatectomy, transurethral resection of the prostate (TURP), for benign prostatic hyperplasia, Transurethral incision of the prostate (TUIP) or bladder neck, Transurethral resection of bladder tumors (TURBT) and cystodiathermy. These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

INDICATIONS FOR USE VAPORIZATION ELECTRODE:

The Omnitech HF Vaporization electrode for plasma vaporization is a bipolar instrument designed and intended for use in urological surgical procedures involving vaporization, ablation, coagulation, cutting, removal of soft tissue and coagulation where hemostasis is required. The specific soft tissue indications include: Use in the prostate, bladder, and bladder neck. The specific treatment indications include benign prostate hyperplasia (BPH), bladder cancer, tumors, lesions and neoplasms. The specific urological indications include Transurethral Electro vaporization (TUVP), (TVP), (TUEVP) also known as Transurethral Vapor Resection of the prostate (TUVRP), Transurethral Vaporization in Saline (TUVis). These devices are intended to be used in an irrigated environment. These devices are not intended to be used in treating cancer of the prostate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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