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

November 19, 2014

ArthroCare Corporation
Ms. Ashley Johnston
Regulatory Affairs Specialist
7000 West William Cannon Drive
Austin, Texas 78735

Re: K142999
Trade/Device Name: ArthroCare ENT Plasma Wands
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 15, 2014
Received: October 17, 2014

Dear Ms. Johnston:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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 on last page.

510(k) Number *(if known)*
K142999

Device Name
ArthroCare ENT Plasma Wands

Indications for Use *(Describe)*
The ArthroCare ENT Plasma Wands are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal/Laryngeal Indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Tonsillectomy (including palatine tonsils)
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment Of Snoring

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) Summary

ArthroCare Corporation

EVac 70 Xtra and PROcise XP Wands with Integrated Cable

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Ashley Johnston Regulatory Affairs Specialist Phone: 512-385-5762 Fax: 512-895-1489
Date Prepared:	October 15, 2014

Device Name

Proprietary Name:	EVac 70 Xtra Wand with Integrated Cable PROcise XP Wand with Integrated Cable
Common Name:	Electrosurgical devices and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Device Class:	Class II
Product Code:	GEI
CFR Section:	21 CFR 878.4400

Predicate Device

ENT Plasma Wands

EVac 70 Xtra Wand with Integrated Cable	K070374 (April 25, 2007)
PROcise XP Wand with Integrated Cable	K070374 (April 25, 2007)

Description

The ArthroCare ENT Plasma Wands are bipolar, high frequency electrosurgical devices designed for use in otorhinolaryngology (ENT) surgery. The Wands consists of a single or multiple active electrode(s) located on the distal end of the shaft, a suction line, a saline line, and an injection molded, medical grade plastic handle with integrated cable at the proximal end of the wand. A cable connector is attached to the end of the cable, which connects the wand directly to the ArthroCare

Coblator II Controller (CII Controller). The EVac 70 Xtra and PROcise XP Wands with Integrated Cable (EVac 70 Xtra and PROcise XP Wands) are a part of the ENT Plasma Wand family previously cleared under 510(k) K070374 for a change in indications; the integrated cable design was first cleared under 510(k) K033257.

Consistent with the predicate cleared under 510(k) K070374, the ENT Plasma Wands are only compatible with the CII Controller. The controller is designed to deliver radiofrequency energy to the active electrode(s) at the distal end of the wand. Each Wand is designed for soft tissue procedures where tissue resection, ablation, coagulation, and hemostasis are desired. The Wands are provided sterile, and are intended for single use.

This 510(k) seeks clearance for the following changes:

- Addition of an Electronic Use-Limiting (EUL) feature to the integrated cable which will limit the re-use of these single-use disposable Wands.
- A change in the design of the cable connector which mates with the Controller.
- Implementation of Ethylene Oxide (EO) sterilization in lieu of e-Beam sterilization.

Intended Use/Indications For Use

The ArthroCare ENT Plasma Wands are indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including adenoidectomy, cysts, head, neck, oral, and sinus surgery, mastoidectomy, myringotomy with effective hemorrhage control, nasal airway obstruction by reduction of hypertrophic nasal turbinates, nasopharyngeal/laryngeal indications including tracheal procedures, laryngeal polypectomy, and laryngeal lesion debulking, neck mass, papilloma keloids, submucosal palatal shrinkage, submucosal tissue shrinkage, tonsillectomy (including palatine tonsils), traditional uvulopalatoplasty (RAUP), tumors, tissue in the uvula/soft palate for the treatment of snoring.

Summary of Technological Characteristics

No changes or modifications have been made to the design of the distal Wand elements (i.e. electrodes, materials, shaft, and insulation), indications for use, technology, or principle of operation previously cleared in 510(k) K070374. The following table represents a summary of the technological characteristics of the modified ENT Plasma Wands.

	PREDICATE DEVICE: ENT Plasma Wands (K070374)	**PROPOSED DEVICE**: Modified ENT Plasma Wands ▪ EVac 70 Xtra Wand with IC ▪ PROcise XP Wand with IC
Intended Use	The ArthroCare ENT Plasma Wands are intended for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery.	Same
Patient Usage	Single Use	Same
Sterilization	Radiation	EO
Electrical Safety/EMC	IEC 60601-2-2 compliant	Same
Use-limit Feature	No	Yes

Cable connector design	Press-fit	Snap-fit

Performance Data

Performance bench testing, including functional testing, ablation life, coagulation, software testing, biocompatibility, and electrical safety testing were performed on the proposed EVac 70 Xtra and PROcise XP Wands with Integrated Cable, which demonstrated the new cable assembly met the required specifications.

Ablation and coagulation testing were performed in animal tissue to compare the tissue effects using the modified Wands as compared to the predicate devices to support substantial equivalence. No clinical data is required to support the proposed change.

Summary

All testing demonstrates that the EVac 70 Xtra and PROcise XP Wands with Integrated Cable perform as intended and have acceptable mechanical properties when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are unchanged from the predicate devices, the EVac 70 Xtra and PROcise XP Wands with Integrated Cable are substantially equivalent. The modifications to the design and sterilization method do not affect the safety or efficacy of the devices.