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

September 29, 2016

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

Re: K162126
Trade/Device Name: Ambient® KVac™ Wand with Integrated Finger Switches (Ambient KVac IFS); KVac™ Integrated Cable Wand (KVac ICW)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 29, 2016
Received: August 1, 2016

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 Part 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 Parts 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,

Christopher J. Ronk -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 below.

510(k) Number *(if known)*
K162126

Device Name
ArthroCare® KVac® Integrated Cable Wand
ArthroCare Ambient® KVac Wand with Integrated Finger Switches

Indications for Use *(Describe)*
Please see attached.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

The KVac Wands (Ambient KVac IFS and KVac ICW) are indicated for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

Joint	Ablation/Debridement	Excision/Resection	Coagulation
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	▪ Articular Cartilage ▪ Bursectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon	▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon	▪ Articular Cartilage ▪ Ligament ▪ Tendon
Hip		▪ Acetabular Labrum	
Knee	▪ ACL/PCL ▪ Notchplasty	▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy ▪ Meniscectomy ▪ Villusectomy	▪ ACL/PCL ▪ Medial Retinaculum
Shoulder	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoidale Labrum	▪ Glenohumeral Capsule ▪ Rotator Cuff
Wrist		▪ Triangular Fibrocartilage (TFCC)	▪ Carpal Ligaments ▪ Wrist Tendons

510(k) Summary

ArthroCare® Corporation

KVac™ Wands
(Ambient® KVac™ Wand with Integrated Finger Switches and KVac™ Integrated Cable Wand)

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: 512-358-5762 Fax: 512-895-1489
Date Prepared:	September 27, 2016

Device Name

Proprietary Name:	Ambient® KVac™ Wand with Integrated Finger Switches (Ambient KVac IFS); KVac™ Integrated Cable Wand (KVac ICW)
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	II
Product Code:	GEI
Regulation Number:	21 CFR 878.4400

Predicate Device

K083306	Ambient Super MultiVac Wand with Integrated Finger Switches (IFS) of the ArthroCare ArthroWands Family, K083306 (cleared December 10, 2008)

Description

The KVac Wands are bipolar, sterile, high frequency electrosurgical devices designed for ablation, and resection of soft tissue and hemostasis of blood vessels during arthroscopic and orthopedic surgery.

The KVac Wands will be offered in two versions: the KVac Wand with Integrated Cable (KVac ICW) and the Ambient KVac Wand with Integrated Finger Switches (Ambient KVac IFS). The two wands are identical in all design and functional aspects, as well as principle of operation, with the exception of the following:

- Integrated Finger Switches – The Ambient KVac IFS Wand will incorporate finger switches into the handle to activate the ablation and coagulation functions. The KVac ICW Wand is controlled via a foot pedal attached to the Controller (note: the foot pedal may also be used with the Ambient KVac IFS Wand to activate ablation and coagulation functions instead of the Integrated Finger Switches).
- Proprietary Ambient Technology – The Ambient technology provides accurate (± 3 ºC) real time temperature monitoring of the circulating irrigation fluid in the joint space between 20 ºC and 60 ºC and includes a user adjustable alarm set-point. An alarm on the Quantum 2 Controller sounds if the temperature exceeds the pre-set range. Only the Ambient KVac IFS Wand will offer the Ambient® technology. This feature will not be available on the KVac ICW.

Aside from these features, the Wands are identical in all other aspects and are designed for the same intended use. The shafts of the Wands feature a 50 degree bend in the distal end, which terminates in the electrode tip. The electrode tip consists of a flat, tungsten screen welded to Platinum/Iridium lead wires, which pass through an alumina ceramic spacer that serves as a ground. Openings in the electrode screen overlay a spacer suction lumen, which connects with internal suction tubing that runs through and exits the handle and is connected to OR wall suction. Suction is used to draw the tissue closer to the active electrode for optimal ablation and also allows for increased user visibility by removing bubbles and floating tissue generated during tissue ablation. The handpiece is connected to the Quantum/Quantum 2 Controller *via* an integrated cable, which terminates in an 18-pin connector.

Intended Use/Indications for Use

The KVac Wands (Ambient® KVac™ Wand with Integrated Finger Switches and KVac™ Integrated Cable Wand) are indicated for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures.

Joint	Ablation/Debridement	Excision/Resection	Coagulation
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	▪ Articular Cartilage ▪ Bursectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon	▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon	▪ Articular Cartilage ▪ Ligament ▪ Tendon
Hip		▪ Acetabular Labrum	
Knee	▪ ACL/PCL ▪ Notchplasty	▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy ▪ Meniscectomy ▪ Villusectomy	▪ ACL/PCL ▪ Medial Retinaculum
Shoulder	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoidale Labrum	▪ Glenohumeral Capsule ▪ Rotator Cuff
Wrist		▪ Triangular Fibrocartilage (TFCC)	▪ Carpal Ligaments ▪ Wrist Tendons

Technological Comparison to Predicate

The technological characteristics of the proposed subject devices are the same as the predicate device. No changes or modifications have been made to the intended use, fundamental scientific technology,

or principle of operation previously cleared in 510(k) K083306. The following table represents a summary of the technological characteristics:

Parameter	Predicate Devices Ambient Super MultiVac Wand (K083306)	Subject Devices Ambient KVac IFS and KVac ICW Wands	Justification of Differences
Controllers	Quantum 2	Quantum/Quantum 2	Ambient KVac IFS Wand is used with Quantum 2 (for the Ambient technology); KVac ICW Wand is used with Quantum or Quantum 2
Wand Materials			
Electrode Screen/ Lead Wire Material	Electrode screen attached only by epoxy with the legs of the screen bent into the holes of the spacer for connection with lead wires	Electrode screen attached to a ceramic spacer with epoxy and the legs of the screen laser welded to Platinum/ Iridium lead wires which pass through holes in the spacer	Provides additional fixation of screen to wire leads
Active Wire Connection Point	Tungsten	Platinum/Iridium	Platinum/Iridium is more resistant to plasma degradation. No effect on safety or efficacy.
Wand Design			
Shaft Length	137 mm	160 mm	Increased length improves access to anatomical sites (e.g. hip)
Outer Diameter of Shaft	3.8 mm	3.4 mm	The smaller OD allows better access to small joint anatomical spaces (e.g. knee)
Number of Internal Suction Ports	2	3	An increased number of suction ports improve visibility by clearing bubbles.
Screen	Tungsten screen with legs bent into holes in spacer and bonded to spacer with epoxy.	Tungsten screen with welded Pt/Ir leads that are bonded to holes in spacer with epoxy.	Provides additional fixation of screen to wire leads.
Internal Suction Tube Configuration	Stainless steel tube between suction tube and ceramic spacer	Suction tube bonded directly to ceramic spacer	Improves manufacturability of the KVac wands. No effect on safety or efficacy.
Thermocouple Connection	Autosplice	Autosplice and Solder	Improves stability of connection to thermocouple
Tyvek Packaging/ Adhesive	Adhesive layer covers entire back of Tyvek lid	Adhesive is zone-coated around the edge of the Tyvek	Packaging was validated to identical parameters

Performance Testing – Bench

Performance bench testing, including functional testing, ablation life, coagulation, biocompatibility, and electrical safety testing were performed on the KVac Wands, to verify the designs meet performance specifications and to evaluate the performance of the KVac Wands compared to the predicate device.

Performance testing was performed in tissue models representing muscle, cartilage, meniscus, and tendon. High, default and low ablation and coagulation settings were used to compare the amount of tissue removed (ablation depth) and thermal effect depth created. The test results demonstrate that the KVac Wands meet all design and performance specifications and are substantially equivalent to the predicate device.

Performance Testing – Animal

No animal data are included in this submission.

Performance Testing - Clinical

No clinical data are included in this submission.

Substantial Equivalence

Non-clinical performance data such as design verification, , tissue effect testing (histology, thermal margins) demonstrated that the subject devices are substantially equivalent to the predicate devices and are safe and effective when used as intended.

Summary

All testing demonstrates that the KVac Wands perform as intended and have acceptable mechanical properties when used in accordance with its labeling. The KVac Wands are substantially equivalent to the predicate Ambient Super MultiVac Wand with IFS (K083306). The differences between the KVac Wands and the predicate device do not raise any new concerns about the safety or effectiveness of the subject devices.