May 1, 2018

ArthroCare Corporation
Ms. Shruthi Bhat
Regulatory Affairs Specialist II
7000 West William Cannon Drive
Austin, Texas 78735

Re: K180848
Trade/Device Name: AMBIENT Super MULTIVAC 50 Wand with Integrated Finger Switches
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 30, 2018
Received: April 2, 2018

Dear Ms. Bhat:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180848

Device Name

AMBIENT™ Super MULITVAC™ 50 Wand with Integrated Finger Switches

Indications for Use *(Describe)*

See attached below

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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Indications for Use:

The AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures.

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

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K180848

510(k) Summary

AMBIENT° Super MULITVAC° 50 Wand with Integrated Finger Switches

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

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Address: 7000 West William Cannon Drive
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Date Prepared: 30 March 2018

Device Name

Proprietary Name: AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches

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

AMBIENT° Super MULITVAC° 50 Wand with Integrated Finger Switches cleared under 510(k) K083306 (Modification to ArthroCare ArthroWands) on December 10, 2008.

Description

The AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches ("Wand") is a bipolar, high frequency electrosurgical device used for specific indications in orthopedic and arthroscopic surgeries. The AMBIENT° feature provides accurate (± 3° C) real-time temperature monitoring of the circulating irrigating fluid between 20° C and 60° C and includes a user adjustable alarm set point. The Wand is designed for use up to five minutes of cumulative active ablation time at the default set point of 7 and is to be used only with the QUANTUM° 2 Controller ("Controller").

Intended Use/Indications for Use

The AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures.

	Ablation/Debridement	
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	▪ **Articular Cartilage** ▪ **Bursectomy** ▪ **Chondroplasty** ▪ **Fascia**	▪ **Scar Tissue** ▪ **Soft Tissue** ▪ **Synovectomy** ▪ **Tendon**

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

	▪ **Rotator Cuff**
Wrist	▪ **Carpal Ligaments** ▪ **Wrist Tendons**

Summary of Technological Characteristics

Parameter/ Characteristics	**Predicate Device** AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches (K083306)	**Subject Device** AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches
Indications for Use	Resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic procedures.	Same
Arthrocare Controller(s)	Quantum 2	Same
Wand Materials		
Materials Biocompatible	Yes	Same
Active Electrode	Tungsten	Same
Electrode Insulation	Polyolefin	Same
Spacer	Alumina	Same
Shaft (Return Electrode)	Stainless Steel	Same
Suction Tubing/ Saline Delivery Tubing	PVC & Nylon	Same
Suction / Irrigation Line Connector	PVC	Same
Adhesive	Epoxy, Cyanoacrylate, UV Adhesive	Same
Cable Assembly Design	The cable assembly is composed of a cable that at one end contains a unique connector with embedded PCBA to mate with the RF generator/controller, and at the other end contains a PCBA that is housed within the handle of the	Same

	wand. The cable contains 8 conductors. Two (2) of the conductors transmit the RF power from the RF generator. Six (6) of the conductors are used for signal transmission. The PCBAs contain wand operating parameters and process fingerswitch and thermistor inputs and communicate with the RF generator via the 6 signal transmission conductors.	
Resistor R1 in the connector of the Integrated Cable	***576 ohms***	***1210 ohms***
Resistor R2 in the connector of the Integrated Cable	1050, 1210, 1300, 1400, 1500, 1620, 1740, or 1870 Ohms.	Same
External Insulation (Return Insulation)	Polyester	Same
Handle Material	Polycarbonate, Polyolefin (finger switch material)	Same
Handle Length	5.75	Same
Wand Temperature Sensor (non-body contacting)	Copper, Constantan	Same
Packaging	Tyvek Lid 09570	Same
Cable Wrap for Packaging	Paper	Same
Physical Specifications (Wands)		
Total Length	11 inches	Same
Distal Bend Angle	43 degrees	Same
Number of Electrodes	1	Same
Number of Internal Suctions Channels	1	Same
Wand Features		
Electrode Configurations	Screen	Same
Electrode Articulation	0 degrees	Same
Shaft Rotation	0 degrees	Same
Spacer Configurations	Single Lumen	Same

Rigid Construction	Yes	Same
Suction and/ or Irrigation	Suction	Same
Packaged Sterile	Yes	Same
Single Use Disposable	Yes	Same
Operates in saline environment	Yes	Same
Bipolar/ monopolar	Bipolar	Same
Activation	Foot Control or Wand with Integrated Finger Switch	Same
Coagulation Voltage Setting	Adjustable (3 set points), 2 Active Set Points	Same
Use Limiting Scheme	***Activation of fuse allows up to 40 minutes of use and an overall connection time up to 8 hours***	***Activation of fuse allows up to 7 minutes of use and an overall connection time up to 8 hours***
Performance Specifications		
Environmental Exposure	2 hours in Normal Saline or blood	Same
Sterilization	Irradiation	Same
Wand Temperature Sensor	T-Type thermocouple with range of 20-60º C ± 3 º C	Same

Clinical Data

No clinical data are included in this submission.

Performance Data

Performance bench testing, including functional testing, IEC testing, Ambient accuracy, ablation performance, use-limiting and coagulation testing was performed on the subject device which demonstrates that the subject device continues to meet the design requirements and supports substantial equivalence with the predicate device. The tests are listed below:

- Transit Conditioning
- Visual Inspection Post-Transit
- IEC Testing
- Ambient Accuracy Testing
- Ablation Performance Testing at Default Set Point and Suction
- Coagulation Testing

- Ablation Performance Testing at Default Set Point & Suction & Use Limiting Feature
- Use-Limiting Feature

All devices used for verification testing were sent to an ArthroCare approved supplier for sterilization.

Conclusion

All testing demonstrates that the AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches performs as intended and has acceptable performance when used in accordance with its labeling. As the indications for use, contraindications, principle of operation and technology are unchanged from the predicate device, except for the Integrated Cable, the subject device, AMBIENT° Super MULTIVAC° 50 Wand with Integrated Finger Switches, is substantially equivalent to the predicate device.