January 24, 2019

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

Re: K183346
Trade/Device Name: FLOW 90º Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 30, 2018
Received: December 3, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

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)*

K183346

Device Name
FLOW 90 Wand

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)

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 for FLOW90° Wand

The FLOW 90 Wand, used with the WEREWOLF COBLATION System, is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures:

Joint	Ablation/Debridement	Excision/Resection
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
Hip		• Acetabular Labrum
Knee	• ACL/PCL • Notchplasty	• Capsular Release • Cartilage Flaps • Discoid Meniscus • Lateral Release • Meniscal Cystectomy • Meniscectomy • Villusectomy
Shoulder	• Acromioplasty • Subacromial Decompression	• Frozen Shoulder Release • Glenoid Labrum
Wrist		• Triangular Fibrocartilage

510(k) Summary

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.

1. **General Information**

Submitter Name:	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Shruthi Bhat M.Sc., MS Regulatory Affairs Specialist II Arthrocare Corporation 7000 West William Cannon Drive Austin, TX 78735 Phone: (512) 895-1295 Email: shruthi.bhat@smith-nephew.com Fax: 512-895-1489
Date Prepared	30 November 2018

2. **Device Name**

Proprietary Name:	FLOW 90° Wand
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

3. **Predicate Device**

FLOW° 50 Wand cleared under K162074.

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4. Description

The FLOW 90 Wand (Wand) is a bipolar, RF electrosurgical device designed for resection, ablation, and coagulation of soft tissue, and hemostasis of blood vessels in arthroscopic and orthopedic procedures. Similar to the predicate device FLOW 50 Wand (K162074), FLOW 90 Wand is designed to be exclusively used with WEREWOLF° COBLATION° System (K162074).

The FLOW 90 Wand consists of a handle, shaft, integrated cable, and suction tubing. The integrated cable and suction tubing are attached at the proximal end of the handle and connect to the WEREWOLF Controller (part of the WEREWOLF Coblation System) and the Fluid Outflow Regulator of the Controller, respectively. No design changes have been made to the WEREWOLF Controller to support the use of the Flow 90 Wand.

5. Intended Use/Indications for Use

The FLOW 90° Wand, used with the WEREWOLF COBLATION System, is indicated for the resection, ablation, and coagulation of soft tissues 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**	▪ **Meniscal Cystectomy** ▪ **Meniscectomy** ▪ **Villusectomy**

	▪ **Discoid Meniscus** ▪ **Lateral Release**
Shoulder	▪ **Frozen Shoulder Release** ▪ **Glenoid Labrum**
Wrist	▪ **Triangular Fibrocartilage (TFCC)**

6. **Comparison between subject device and predicate device:**

The technological characteristics of the proposed FLOW 90 Wand are the same as the predicate FLOW 50 Wand.

The main technological similarities between the subject FLOW 90 Wand and predicate FLOW 50 wand are listed below:

- COMPATIBILITY WITH THE WEREWOLF COBLATION SYSTEM: Both the FLOW 90 Wand and the FLOW 50 Wand are to be used in conjuction with the WEREWOLF COBLATION System.
- WAND FEATURES: Both the FLOW 90 Wand and the FLOW 50 Wand are bipolar, have Ambient feature, use-limiting feature, suction feature and can be activated using either a fingerswitch or a footpedal.
- WAND SPECIFICATIONS: Both the FLOW 90 Wand and the FLOW 50 Wand have identical wand specifications for suction ports, number of active electrodes, total length and handle length and outer diameter of the shaft.
- PATIENT–CONTACTING MATERIALS: Except for the adhesive, both the FLOW 90 Wand and the FLOW 50 Wand have similar patient-contacting materials for the ceramic space, shaft, shaft insulation, internal suction tubing and suction tube set.
- PACKAGING: Both the FLOW 90 Wand and the FLOW 50 Wand are sterile, disposable and are for single-use only.

No changes or modifications have been made to the intended use, fundamental scientific technology, or principle of operation which was previously cleared in 510(k) K162074.

The main technological differences between the subject FLOW 90 Wand and predicate FLOW 50 wand are listed below:

- DISTAL TIP: The distal tip of the FLOW 90 Wand was changed to optimize performance with respect to tissue effect, ablation rate, and visualization.
- SHAFT: The shaft of the FLOW 90 Wand features a longer shaft length than the FLOW 50 Wand (137 mm vs 135 mm). The shaft has no angle and a 90° electrode orientation in comparison to the 40° angle and a 70° electrode orientation of the predicate FLOW 50 wand device. The design change provides a variety of clinical access to the clinicians.
- ADHESIVE: HV-10 single part heat cure epoxy will be used as the adhesive in lieu of Loctite 3984 single part heat cure epoxy.
- ELECTRODE: The FLOW 90 Wand uses a metal injection molded (MIM) electrode with 95% tungsten alloy and a single-piece electrode construction while the FLOW 50 Wand uses a tungsten sheet electrode. The MIM electrode design has been previously approved via 510(k) K161481 (Ambient HipVac 50 Wand with Integrated Finger Switches) and enables enhanced manufacturability. The FLOW 90 Wand also features a wider and thicker electrode when compared to the FLOW 50 wand.
- STERILIZATION: The FLOW 90 Wand will be sterilized using Ethylene Oxide unlike FLOW 50, which is sterilized using Electron Beam.

7. Performance Testing

Performance testing including software verification and validation, non-clinical testing (Ambient accuracy, ablation testing, use-limiting testing, design verification, electrical safety testing and biocompatibility testing) and pre-clinical testing were performed on the FLOW 90 Wand in conjunction with the WEREWOLF (RF20000) Controller to demonstrate the subject wand meets the established design criteria and supports substantial equivalence with the predicate device.

Pre-clinical bench testing (ex vivo testing) was performed across multiple tissue models (muscle, tendon, cartilage and meniscus) to verify substantial equivalence to the predicate device in terms of thermal effects.

Based on all the testing performed, the FLOW 90 Wand was found to meet all design and performance specifications and no new safety and efficacy issues were raised as compared to the predicate device.

8. **Performance Testing – Animal**

No animal data are included in this submission.

9. **Performance Testing - Clinical**

No clinical data are included in this submission.

10. **Conclusion**

All testing demonstrates that the FLOW 90 Wand performs as intended and has acceptable performance when used in accordance with its labeling.

Arthrocare Corporation evaluated the indications for use, materials, technology, design and performance specification requirements of the subject device to demonstrate that the FLOW 90 Wand is substantially equivalent to the predicate device for its intended use, principle for operation and fundamental scientific technology.