May 8, 2024

ArthroCare Corporation
Srividya Pothana
Senior Regulatory Affairs Specialist
7000 West William Cannon Drive
Austin, Texas 78735

Re: K240964
Trade/Device Name: FLOW 90◊ Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 8, 2024
Received: April 9, 2024

Dear Srividya Pothana:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.05.08 13:53:41 -04'00'

Long H. Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240964

Device Name

FLOW 90◊ Wand

Indications for Use *(Describe)*

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

All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)
- Ablation/ Debrideement - (Articular Cartilage, Bursectomy, Chondroplasty, Fascia, Ligament, Scar,Tissue, Soft Tissue, Synovectomy, Tendon)
- Excision/Resection (Articular Labrum, Capsule, Cysts, Ligament, Loose Bodies, Plica Removal, Scar Tissue, Soft Tissue, Synovial Membrane,Tendon)

Hip
- Excision/Resection - (Acetabular Labrum)

Knee
- Ablation/ Debrideement - (ACL/PCL, Notchplasty)
- Excision/Resection - (Capsular Release, Cartilage Flaps, Discoid Meniscus, Lateral Release, Meniscal Cystectomy, Meniscectomy, Villusectomy)

Shoulder
- Ablation/ Debrideement - (Subacromial Decompression)
- Excision/Resection - (Frozen Shoulder Release, Glenoid Labrum)

Wrist
- Excision/Resection - (Triangular Fibrocartilage)

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.

Special 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.

GENERAL INFORMATION

Submitter Name	ArthroCare Corporation
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person	Srividya Pothana Senior Regulatory Affairs Specialist Arthrocare Corporation 7000 West William Cannon Drive Austin, TX 78735 **Phone:** 512-391-3900 **Email:** Srividya.pothana@smith-nephew.com **Fax:** 512-391-3901
Date Prepared	**April 8, 2024**

DEVICE NAME

Subject Device Proprietary Name	FLOW 90◊ Wand
Model/Catalog Number	72290038
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(S)

FLOW 90◊ Wand cleared under K183346.

SUBJECT DEVICE DESCRIPTION

The FLOW 90 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. The FLOW 90◊ Wand is compatible with Qualified controllers (WEREWOLF◊ COBLATION◊ Systems (includes WEREWOLF◊ (K162074), WEREWOLF◊ ENT, (K192027) and WEREWOLF◊ + (K210423)) and INTELLIO◊ SHIFT ◊ System (K232290)).

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 Qualified Controller and the Fluid Outflow Regulator of the Controller, respectively. No design changes have been made to the Qualified Controllers to support the use of the modified FLOW 90 Wand.

INTENDED USE/INDICATIONS FOR USE

The FLOW 90◊ Wand, used with a qualified controller 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	▪ **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** ▪ **Glenoid Labrum**	
Wrist	▪ **Triangular Fibrocartilage**	

COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE(S)

Technological Differences with Predicate

This Special 510(k) submission supports the design changes within the subject device's handle assembly and interface between finger switches and button pad to improve the device's ability to withstand clinical conditions related to fluid exposure and finger switch (button) actuation. A new packaging tray was also qualified as part of this submission to better secure the wand at its proximal end during transit.

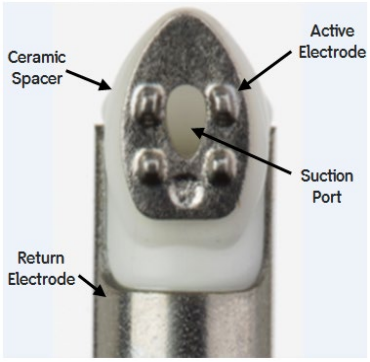
Some additional differences between subject FLOW 90 Wand and predicate FLOW 90 (K183346) included as part of Letter to Files submissions are:

- Indications for use - Shoulder acromioplasty is removed as an indication of use, this change does not affect the intended use, safety, and effectiveness of the device.
- Controller - The compatible qualified controllers include WEREWOLF ENT, WEREWOLF+ and INTELLIO SHIFT.

The modifications made to support the changes do not impact the device's intended use, fundamental scientific technology, and principle of operation and is substantially equivalent to previously cleared **K183346** 510(k) submission.

Technological Similarities with Predicate

Parameter	**PREDICATE DEVICE**: FLOW 90◊ Wand 510(k) K183346	**SUBJECT DEVICE**: FLOW 90 ◊ Wand
Product Code	GEI	Same

CFR	21 CFR 878.4400	Same
Prescription Use Only	Yes	Same
Representation		Same
Intended Use	Resection, ablation, and coagulation of soft tissues andhemostasis of blood vessels inindicated arthroscopic and orthopedic procedures.	Same
Compatible with WEREWOLF◊ COBLATION◊ SYSTEM	Yes	Same
Specifications		
Distal Tip		Same
Active Electrode Configuration	95% Tungsten alloy MIM (metal injection molded) electrode with four molded, raised features to help provide tactile feedback to the surgeon. Mating features that interact with spacer. Electrode is bonded to spacer with epoxy.	Same

Shaft Working Length	137 mm	Same
Tubing/Shaft Angle near the Wand Tip	No Angle	Same
Electrode Orientation relative to Shaft	90°	Same
Number of Suction Ports	1	Same
Number of Active Electrodes	1	Same
Recommended Active Ablation Time	Active ablation time per Mode (not additive): Lo Mode: 7 minutes. Med Mode: 7 minutes Hi Mode: 7 minutes	Same
Wand Features		
Bipolar/ Monopolar	Bipolar	Same
Activation Method	Foot Pedal or Finger Switch	Same
Use-limiting Feature	Yes (software controlled)	Same
Sterilization and Packaging		
Sterilization	Ethylene Oxide	Same
Packaged Sterile/ Single Use Disposable	Sterile, Single Use, Disposable	Same

Some additional similarities between subject FLOW 90 Wand and predicate K183346 510(k) submission include:

Patient Contacting Materials: Both subject and predicate FLOW 90 Wands have equivalent patient contacting materials for the ceramic spacer, shaft, shaft insulation, adhesive, internal suction tubing and suction tube set.

Wand Specifications: The subject and predicate have the same wand specifications for suction ports, number of electrodes and handle lengths and outer diameter of the shaft.

NON-CLINICAL Testing

Electrical Safety: Basic safety and performance testing was performed on the proposed FLOW 90 Wand to demonstrate electrical, mechanical and functional capabilities in accordance with IEC 60601-1 and IEC 60601-2-2.

Bench testing: Mechanical Integrity and Functional Testing was performed, including testing results for flow rate, fluid ingress, suction tube kinking, and finger switch testing which are identified in the attachments.

Additionally, the new packaging tray was validated in accordance with ASTM D4169-DC13, ISO 11607-1, and ISO 11607-2.

Testing demonstrated the safety and efficacy of subject FLOW 90 Wand is substantially equivalent to its predicate device. All design inputs have been met and the testing performed did not introduce any new questions of safety or effectiveness.

CONCLUSION

All testing demonstrates that the proposed device performs as intended and has acceptable performance when used in accordance with its labeling. As the intended use, principle of operation, performance and fundamental scientific technology are unchanged from the predicate device the subject FLOW 90 Wand is substantially equivalent to the predicate device.