March 30, 2026

ArthroCare Corporation
Alexander Brankner
International Regulatory Affairs Manager
7000 W. William Cannon Dr.
Austin, Texas 78735

Re: K254122
Trade/Device Name: FLOW FLEXTEND Wand (72290039)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 13, 2026
Received: February 17, 2026

Dear Alexander Brankner:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2026.03.30 21:47:08 -04'00'

James Jang, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254122

Please provide the device trade name(s).

FLOW FLEXTEND Wand (72290039)

Please provide your Indications for Use below.

The FLOW FLEXTEND 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:

All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)
Ablation/Debridement: 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/Debridement: ACL/PCL, Notchplasty.
Excision/Resection: Capsular release, Cartilage Flaps, Discoid Meniscus, Lateral release, Meniscal Cystectomy, Meniscectomy, Villusectomy.

Shoulder
Ablation/Debridement: Subacromial Decompression.
Excision/Resection: Frozen Shoulder Release, Glenoid Labrum.

Wrist
Excision/Resection: Triangular Fibrocartilage.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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.

35.1 GENERAL INFORMATION

Submitter Name ArthroCare Corporation

Address 7000 West William Cannon Drive
Austin, TX 78735

Contact Person Alexander Brankner
International Regulatory Affairs Manager
ArthroCare Corporation
7000 West William Cannon Drive Austin, TX 78735

Phone: 512-673-3090
Email: Alexander.Brankner@smith-nephew.com

Date Prepared 19 December 2025

35.2 DEVICE NAME(S)

Subject Device Proprietary Name	FLOW FLEXTEND◇ Wand
Common Name	Electrosurgical devices and accessories
Classification Name	Electrosurgical, cutting & coagulation & accessories
Device Class	Class II
Product Code	GEI
CFR Section	CFR 878.4400

35.3 PREDICATE DEVICE(S)

FLOW 90◇ Wand cleared under K240964.

REFERENCE DEVICE(S)

SIDEWINDER Wand cleared under K162074.
This predicate has not been subject to a design-related recall.

EFLEX ABLATOR Wand cleared under K003893.
This predicate has not been subject to a design-related recall.

35.4 SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain clearance for the FLOW FLEXTEND◇ Wand intended to be used with the previously cleared WEREWOLF COBLATION Systems (WEREWOLF◇ COBLATION◇ system (K162074), WEREWOLF◇ COBLATION◇ System (K192027), WEREWOLF◇+ COBLATION◇ System (K210423) and INTELLIO◇ SHIFT◇ System (K232290). The predicate device, Flow 90◇ Wand (K240964) is included with intended use, principle of operation, core design, and materials identical to the subject device.

35.4.1 FLOW FLEXTEND Wand

The FLOW FLEXTEND Wand is a single use, bipolar, radiofrequency (RF) electrosurgical device designed for specific indications in orthopedic and arthroscopic procedures. The wand is designed for compatibility with the existing hardware and software of the WEREWOLF Controllers (WEREWOLF COBLATION System (K162074), WEREWOLF COBLATION System (K192027), WEREWOLF+ COBLATION System (K210423), and the INTELLIO SHIFT System (P/N 72290150). No design changes have been made to the WEREWOLF COBLATION System or INTELLIO SHIFT System to support the use of the FLOW FLEXTEND Wand.

The FLOW FLEXTEND Wand consists of a handle with integrated finger switches, shaft, integrated cable, and suction tubing. The integrated cable and suction tubing are attached at the proximal end of the handle/handpiece and connect to the WEREWOLF Controller (part of the WEREWOLF Coblation System) and the Fluid Outflow Regulator of the Controller, respectively.

- The integrated cable is compatible with WEREWOLF and INTELLIO SHIFT Systems (Controllers); the cable connector is specific and proprietary to the compatible systems and is designed so the Wand cannot be plugged into any other commercial system.

- The integrated suction tubing is compatible with Integrated Fluid Control Module (FLOW-IQ Pump) of WEREWOLF and INTELLIO SHIFT Controllers and allows connection with saline source. The suction tubing has color-coded and keyed inserts that correspond to matching receptacles on the FLOW-IQ Pump so the tubing cannot be connected incorrectly.

The Wand may be activated using integrated finger switches directly on the handle or by using the compatible Foot Control system accessory for each Controller. The Wand is provided sterile (via ethylene oxide) and is single use only. When used with both the WEREWOLF and INTELLIO SHIFT systems the wand is designed to work in ablation mode for tissue removal, resection, and in coagulation mode to create hemostasis of blood vessels encountered during arthroscopic and orthopedic surgery. The effect is dependent on the selected Controller settings.

35.5 INTENDED USE/INDICATIONS FOR USE

The indications for use of the subject wand are identical to its predicate, FLOW 90◇ Wand, and are as follows: The FLOW FLEXTEND◇ 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:

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	• Subacromial Decompression	• Frozen Shoulder Release • Glenoid Labrum
Wrist		• Triangular Fibrocartilage

Figure 35.1: FLOW FLEXTEND◇ Wand Indications for Use

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

At a high level, the subject and predicate devices are based on the following same technological elements:

Table 35.1 Summary of comparison of the Technological Features of Subject and Predicate devices

Parameter	Predicate: **FLOW 90 (K240964)**	Subject Device: **FLOW FLEXTEND**	Rationale: **Subject vs Predicate**
Manufacturer	Arthrocare Corporation	Arthrocare Corporation	No Difference
Product Code	GEI	GEI	No Difference
CFR	21 CFR 878.4400	21 CFR 878.4400	No Difference
Classification	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	No Difference
Prescription Use Only	Yes	Yes	No Difference
Compatible Controllers	WEREWOLF, WEREWOLF ENT, WEREWOLF +, INTELLIO SHIFT	WEREWOLF, WEREWOLF ENT, WEREWOLF +, INTELLIO SHIFT	No Difference
Environment of Use	Healthcare Facility	Healthcare Facility	No Difference
Distal Tip Components	Suction lumen, active electrode, spacer, return shaft, and shaft insulation	Suction lumen, active electrode, spacer, return shaft, and shaft insulation	No Difference
Duration and Type of Contact	Externally communicating device with direct, limited (≤24 hours) contact to tissue	Externally communicating device with direct, limited (≤24 hours) contact to tissue	No Difference
Total Length (Shaft Working Length+ Handle Length)	11.5 inches (5.5 inches + 6.0 inches)	14.5 inches (7.0 inches + 7.5 inches)	The increased device length accounts for different working length and handle length.
Integrated Suction, Saline and Cable	Integrated suction tube that interfaces with the peristaltic pump on the RF generator/controller.	Integrated suction tube that interfaces with the peristaltic pump on the RF generator/controller.	No Difference
Electrode Orientation Relative to Shaft	90°	45°	Different orientations provide a variety of clinical access
Adjustable Shaft Angle Near the Wand Tip	N/A (fixed shaft)	Adjustable angle, range -10° to +65°	Different angles provide a variety of clinical access.
Number of Suction Ports	1	1	No Difference
Number of Active Electrodes	1	1	No Difference
Bipolar	Bipolar	Bipolar	No Difference
Activation Method	Foot Pedal or Finger Switch	Foot Pedal or Finger Switch	No Difference
Use-limiting Feature	Yes (software controlled)	Yes (software controlled)	No Difference
Embedded Software	Yes	Yes	No Difference

Available Modes and Levels	Coblation (Ablation): Lo-, Lo•, Lo+, Med-, Med•, Med+, Hi-, Hi•, Hi+ Ø (zero output, INTELLIO SHIFT only) Coagulation: Coag•, Coag+ Ø (zero output, INTELLIO SHIFT only) Vacuum: VAC	Coblation (Ablation): Lo-, Lo•, Lo+, Med-, Med•, Med+, Hi-, Hi•, Hi+ Ø (zero output, INTELLIO SHIFT only) Coagulation: Coag•, Coag+ Ø (zero output, INTELLIO SHIFT only) Vacuum: VAC	No Difference
Sterilization	Ethylene Oxide	Ethylene Oxide	No Difference
Packaged Sterile/ Single Use Disposable	Sterile, Single Use, disposable	Sterile, Single Use, disposable	No Difference

35.7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE(S)

At a high level, the subject and reference devices are based on the following same technological elements:

Table 35.2 Summary of comparison of the Technological Features of Subject and Reference devices

Parameter	Subject Device: **FLOW FLEXTEND**	Reference Device 1: **SIDEWINDER (K162074)**	Reference Device 2: **EFLEX ABLATOR (K003893)**	Rationale: **Subject vs Reference**
Product Code	GEI	GEI	HRX GEI	SIDEWINDER: No difference. EFLEX ABLATOR: Subsequent product code (GEI) aligns to subject device.
CFR	21 CFR 878.4400	21 CFR 878.4400	21 CFR 888.1100 21 CFR 878.4400	SIDEWINDER: No difference. EFLEX ABLATOR: Subsequent product code (GEI) aligns to electrosurgical cutting and coagulation device and accessories.

Classification	Electrosurgical, Cutting & Coagulation & Accessories	Electrosurgical, Cutting & Coagulation & Accessories	Arthroscope Electrosurgical, Cutting & Coagulation & Accessories	SIDEWINDER: No difference. EFLEX ABLATOR: Subsequent product code (GEI) aligns to electrosurgical cutting and coagulation device and accessories.
Handle Length	6 inches	5 inches	5.5 inches	The different handle lengths are due to different shaft deflection mechanisms.
Shaft Working Length	183 mm	229 mm	236 mm	Different shaft working lengths provide variety of clinical access.
Fixed vs. Articulating Tip	Articulating	Articulating	Articulating	No Difference
Degree of Tip Flexion	Adjustable angle, range -10° to +65°	Adjustable angle, range 0° to +80°	Adjustable angle, range -20° to +110	Different degrees of tip flexion provide a variety of clinical access. The total subject device tip flexion range (-10° to +65°) is within the total range of the reference devices (-20° to +110).
Deflection Mechanism User Interface	Present at distal end of handle. Wingnut composed of 2 wings, oriented 180°.	Present on bottom of handle. Pivoting trigger arm with static finger/thumb support arm	Present at proximal end of handle. Pivoting trigger arm with static finger/thumb support arm	Both interfaces enable manual adjustment of the shaft angle at distal tip.
Deflection Shaft Angle Hold	Holds user-set articulation angle without need to actively grip mechanism.	Requires user to actively hold articulation angle.	Requires user to actively hold articulation angle.	Shaft angle hold enables user to continue treatment without actively engaging mechanism.

35.8 BIOCOMPATABILITY

The biocompatibility evaluation for the FLOW FLEXTEND◇ Wand was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process" and the 2023 FDA Guidance Document on Use of ISO 10993-1. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Chemical Characterization Testing

The FLOW FLEXTEND◇ Wand is categorized per ISO 10993-1: 2018 as an externally communicating device with direct, limited (≤24 hours) contact to tissue/bone/dentin.

35.9 STERILIZATION

The FLOW FLEXTEND◇ Wand is sterilized utilizing 100% Ethylene Oxide (Eto or EO) gas via an existing validated EO Cycle. The evaluation and adoption are based on the principles outlined in AAMI TIR28:2016/(R)2024. The sterilization method ensures a minimum sterility assurance level of 10^{-6}.

The WEREWOLF COBLATION Systems and INTELLIO SHIFT System are provided non-sterile.

35.10 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATABILITY (EMC)

Electrical safety and EMC testing were conducted on the FLOW FLEXTEND◇ Wand, which is used with WEREWOLF COBLATION Systems and INTELLIO SHIFT System. The system complies with the IEC 60601-1 and IEC 60601-2-2 standards for safety and the IEC 60601-1-2 standard for EMC.

35.11 SOFTWARE

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." Per the guidance document the software for this device requires basic documentation.

35.12 BENCH TESTING

The following bench testing was conducted for the FLOW FLEXTEND◇ Wand to assure that the device operates within the predefines design specifications.

- Coagulation Performance
- Ablation Performance
- Active Life
- Suction Performance
- Mechanical testing
- IEC/EMC testing
- Functional tests

35.13 EX-VIVO STUDY

Pre-clinical (ex vivo) testing was conducted on the tissue models representing muscle (myocardium), cartilage, meniscus, and tendon using predicate (FLOW 90 Wand) and the subject, FLOW FLEXTEND◇ Wand. The Thermal effect depth (maximum depth), Total thermal effect width (maximum width) and Ablation depth (maximum depth, muscle only) of the FLOW FLEXTEND◇ Wand were substantially equivalent to the predicate FLOW 90 Wand in both the ablation and coagulation settings.

35.14 CLINICAL TESTING

No clinical tests were included as part of this submission.

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 FLEXTEND◇ Wand is substantially equivalent to the predicate FLOW 90 Wand.