March 25, 2026

ArthroCare Corporation
Srividya Pothana
Senior Regulatory Affairs Specialist
7000 W. William Cannon Dr.
Austin, Texas 78735

Re: K253680
Trade/Device Name: LYNX COBLATION Laryngeal Wand (72290254)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 21, 2025
Received: February 27, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.03.25 15:43:05 -04'00'

Colin K. Chen, 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.	K253680

Please provide the device trade name(s).

LYNX◊ COBLATION◊ Laryngeal Wand (72290254)

Please provide your Indications for Use below.

The LYNX◊ COBLATION◊ Laryngeal Wand is indicated for ablation, resection, and coagulation of soft tissues and hemostasis of blood vessels for otorhinolaryngology (ENT) procedures of the larynx and trachea.

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

- ☒ 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.

GENERAL INFORMATION

Submitter Name ArthroCare Corporation

Address 7000 West William Cannon Drive
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Contact Person Srividya Pothana
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Date Prepared **November 21, 2025**

DEVICE NAME

Subject Device Proprietary Name LYNX◊ COBLATION◊ Laryngeal 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

PREDICATE DEVICE

PROCISE◊ LW PLASMA Wand cleared under K202006.

This predicate has not been subject to a design-related recall.

REFERENCE DEVICE

HALO WAND cleared under K192027

This predicate has not been subject to a design-related recall.

SUBJECT DEVICE DESCRIPTION

The LYNX COBLATION Laryngeal Wand is a single-use, disposable, bipolar, radio frequency, electrosurgical device intended for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) procedures. The device is intended to work with Qualified Controllers (WEREWOLF COBLATION SYSTEM (WEREWOLF ENT and WEREWOLF +). There are no changes to the WEREWOLF Controllers or Irrigation pump for use with LYNX Wand.
The LYNX Wand consists of three integrated lines built into the handpiece that allow the wand to work as intended:

- An integrated suction line allows connection to suction source within the operating environment.
- An integrated saline tube set designed to be compatible with the WEREWOLF flow control module allows connection with saline source within the operating environment.
- An integrated cable compatible with the WEREWOLF controller.

The device operates in Coblation (resection/ablation) and Coagulation (coagulation/hemostasis) modes by using their biopolar configuration to create energy field using a conductive irrigating solution.

INDICATIONS FOR USE

"The LYNX™ COBLATION™ Laryngeal Wand is indicated for ablation, resection and coagulation of soft tissues and hemostasis of blood vessels for otorhinolaryngology (ENT) surgical procedures of the larynx and trachea."

The Indication of Use statement for LYNX Wand differs to the PROCISE LW Wand; Indications for Use statement was revised to reference the applicable anatomical regions of the larynx and trachea, rather than listing each specific procedure and focus on the general device's clinical applications. However, the subject device indications for use statement difference does not alter intended use of the device, nor does it affect the safety and effectiveness of the subject device as the same procedures are encompassed as the predicate device.

INTENDED USE

"The LYNX™ COBLATION™ Laryngeal Wand is intended for ablation, resection, and coagulation of soft tissues and hemostasis of blood vessels in otorhinolaryngology (ENT) procedures.

It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate. It is intended to be used with qualified controllers."

The intended use remains unchanged from the predicate device. The second statement "'It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate" has been incorporated from the Indications for Use section of the predicate device to consolidate all intended use statements in one location. And the third statement, "It is intended to be used with qualified controllers" was added for clarity in labeling to identify all controllers compatible with the subject wand, same as the predicate device.

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:

Parameter	**Subject Device: LYNX COBLATION Laryngeal Wand**	**Predicate Device: PROCISE LW Plasma Wand (K202006)**	**Reference Device: HALO Wand (K192027)**	
Manufacturer	Arthrocare Corporation	Same	Same	No Difference
Product Code	GEI	Same	Same	No Difference
CFR	21 CFR 878.4400	Same	Same	No Difference
Classification	Electrosurgical, Cutting & Coagulation & Accessories	Same	Same	No Difference
Prescription Use Only	Yes	Same	Same	No Difference
Compatible with WEREWOLF◊	Yes	Yes	Yes	No Difference

COBLATION◊ SYSTEM				
Environment of Use	Healthcare Facility	Same	Same	No Difference
Wand Specifications				
Distal Tip Components	suction lumen, active electrode, spacer, return shaft, saline feature and shaft insulation	Same	Same	No Difference
Duration and Type of Contact	externally communicating device with direct, limited (≤24 hours) contact to tissue	Same	Same	No Difference
Working Length	10 inch	8 inch	5 inch	Different working lengths provide a variety of clinical access
Integrated Suction, Saline and Cable	Yes	Yes	Yes	No Difference
Electrode Orientation relative to Shaft	10° away from user	45° towards the user	25° towards the user	The difference in angle improves visualization of active electrode during ablation.
Distal Bend Angle	25°	16°	20°	The increase in angle improves visualization of active electrode during ablation.
Proximal Bend Angle	25°	45°	0°	Improved handling and control of the device during use.

Number of Suction Ports	1	Same	Same	No Difference
Number of Active Electrodes	1	Same	Same	No Difference
Wand Features				
Bipolar	Yes	Yes	Yes	No Difference
Activated with Foot Pedal	Yes	Yes	Yes	No Difference
Use-limiting Feature	Yes	No	Yes	Feature similar to the reference device
Embedded Software	Yes	No	Yes	Feature similar to the reference device
Controller Specifications				
Input Power	100-240VAC	Same	Same	No Difference
Default Ablation Set Point/Output Voltage (Vrms)	"Med•" (286 Vrms at 350 Ohm load)	Set Point 7 (265 Vrms)	"Med•" (175 Vrms)	WW Controller uses Ablation levels. For predicate wand with adapter, uses set points.
Default Coagulation Set Point/Output Voltage	"Coag•" (35 Vrms at 50 Ohm Load)	Set Point 3 (75 Vrms)	"Coag•" (73 Vrms at 150 Ohm Load)	WW Controller uses Coagulation levels. For predicate wand with adapter, uses set points.
Ablation Set Point Range / Output Voltage	"Lo –" - "Hi +" (253-300 Vrms at 350 Ohm load)	Set Points 1-9 (100-300 Vrms)	"Med –" - "Hi +" (167-300 Vrms)	WW Controller uses Ablation levels. For predicate wand with adapter uses set points. Minimum

(Vrms)				setting reflects clinical usage.
Coagulation Set Point Range/ Output Voltage (Vrms)	"Coag •" – "Coag •••" (35-40 Vrms at 50 Ohm Load)	Set Points 1-5 (65-87 Vrms)	"Coag •" – "Coag •••" (73-99 Vrms at 150 Ohm Load)	WW Controller uses Coagulation levels. For predicate wand with adapter, use set points.
Sterilization and Packaging				
Sterilization	Ethylene Oxide	E-Beam Radiation	Ethylene Oxide	Logistical Flexibility
Packaged Sterile/ Single Use Disposable	Sterile, Single Use, Disposable	Same	Same	No Difference

NON-CLINICAL TESTING

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the LYNX device 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 LYNX Wand (ENC055) is categorized per ISO 10993-1: 2018 as an externally communicating device with direct, limited (≤24 hours) contact to tissue/bone/dentin.

Sterilization

The LYNX 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 are provided non-sterile

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LYNX device, which is used with WW Coblation 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.

Software Verification and Validation Testing

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.

Bench testing

The following bench testing was conducted for the LYNX 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

Ex-Vivo Study

Pre-clinical (ex vivo) testing was conducted on a bovine myocardial tissue model using predicate (PROCISE LW Plasma Wand) and the subject, LYNX Wand in accordance with FDA's "Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for

General Surgery", March 9, 2020. Clinical history of the predicate device and coblation technology in larynx and trachea was used to further demonstrate the safety and effectiveness of the subject device.

CLINICAL TESTING

No clinical tests were included as part of this submission.

CONCLUSION

All testing demonstrates that the subject 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 of the subject LYNX Wand is substantially equivalent to the predicate PROCISE LW Wand.