June 26, 2023

Arthrocare Corporation
Pragnya Bakka
Senior Regulatory Affairs Specialist
7000 West William Cannon Drive
Austin, Texas 78735

Re: K230914
Trade/Device Name: ARIS¿ COBLATION¿ Turbinate Reduction Wand (72290113); WEREWOLF COBLATION System (72290144); WEREWOLF+ COBLATION System (72290146)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 2, 2023
Received: June 5, 2023

Dear Pragnya Bakka:

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/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 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 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.26 13:56:49 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230914

Device Name

ARIS◊ COBLATION◊ Turbinate Reduction Wand (72290113);
WEREWOLF COBLATION System (72290144);
WEREWOLF+ COBLATION System (72290146)

Indications for Use *(Describe)*

The ARIS Wand, used with the WEREWOLF COBLATION System, is Indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage.

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.

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510(k) Summary

ARIS◊ COBLATION◊ Turbinate Reduction Wand and WEREWOLF COBLATION Systems

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	Pragnya Bakka Senior Regulatory Affairs Specialist **e-mail:** pragnya.bakka@smith-nephew.com
Date Prepared	March 29, 2023

2 DEVICE NAME(S)

Subject Device Proprietary Name	ARIS◊ COBLATION◊ Turbinate Reduction Wand; and WEREWOLF COBLATION System WEREWOLF+ COBLATION System
Common Name	ARIS Wand, Turbinate Reduction Wand, Electrosurgical devices and accessories
Classification Name	Electrosurgical, cutting & coagulation & accessories
Device Class	Class II
Product Code	GEI
CFR Section	CFR 878.4400

3 PREDICATE DEVICE (s) ArthroCare Turbinator Wand (K122652) compatible with WEREWOLF COBLATION System (K202006)

WEREWOLF COBLATION SYSTEM - K210423

WEREWOLF + COBLATION SYSTEM- K192027

REFERENCE DEVICE: FLOW 90^0 Wand - K183346

4 DEVICE DESCRIPTION

The purpose of this submission is to obtain clearance for the subject device ARIS◊ COBLATION◊ Turbinate Reduction Wand, that is intended to be used exclusively with the WEREWOLF COBLATION Systems; WEREWOLF+ COBLATION system (K210423) and WEREWOLF COBLATION System (K192027).

4.1 ARIS COBLATION Turbinate Reduction Wand:

The ARIS COBLATION Turbinate Reduction Wand (Figure 1) 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) surgery including nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue. There are no changes to the WEREWOLF Controllers or Irrigation pump for use with ARIS Wand.

The ARIS Turbinate Reduction Wand consists of three integrated lines built into the handpiece that allow the wand to work as intended:

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

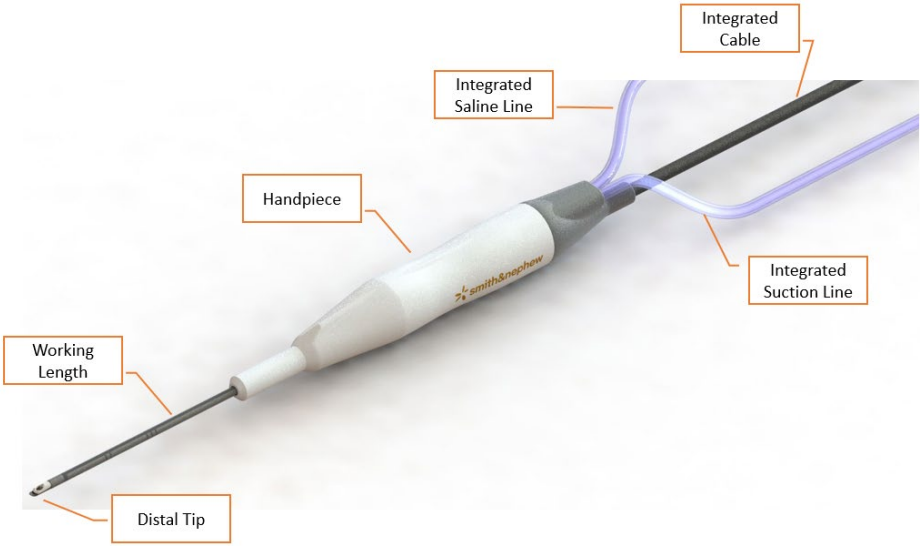

Figure 1 ARIS COBLATION Turbinate Reduction Wand

Note: The subject device, ARIS COBLATION Turbinate Reduction Wand is also referred to as WW Turbinate Wand, ENC504 or ARIS Wand in the test reports associated with this device.

Along with the Wand, a tip clearing component will be included within the packaging of the wand to support removal of clogs.

4.2 WEREWOLF COBLATION Systems

WEREWOLF COBLATION SYSTEM (K192027)
The WEREWOLF COBLATION System consists of:

- A bipolar, radiofrequency (RF) generator (Controller) with Integrated Fluid Module and Operational Interface Screen,
- Re-usable, non-sterile Foot Control (wired or wireless)
- Sterile, disposable, single-use COBLATION Wand(s)
- Reusable, non-sterile power cord.

The WEREWOLF COBLATION System (cleared via 510(k) K192027) utilizes bipolar technology specifically designed for the resection, ablation, and coagulation of blood

vessels in various arthroscopic, orthopedic (cleared via K162074) and otorhinolaryngology (ENT) procedures (cleared via K192074).

The WEREWOLF controller (or WW ENT Controller) is an enclosed unit with incorporated software that runs both the delivery of radiofrequency energy as well as a Graphical User Interface which the user can control various modes, levels, volume, etc. Ports for connecting the compatible Wands and the Foot Control are located on the front panel. An optional wireless Foot Control can be installed. The Controller also incorporates a peristaltic Integrated Fluid Control Module, which provides dynamic control of saline flow (inflow or outflow) to or from the surgical site. The system offers five distinct Modes of Operation (cleared via K162074) for arthroscopic and orthopedic procedures: Hi (Ablation), Med (Ablation), Lo (Ablation), Vac (Vacuum), and COAG (Hemostasis), and four modes for ENT procedures (cleared via K192027).

WEREWOLF+ COBLATION SYSTEM (K210423)

The WEREWOLF COBLATION System consists of:

- A bipolar, radiofrequency (RF) generator (COBLATION System) with Integrated Fluid Module (FLOW IQ™ Pump) and Operational Interface Screen.
- Re-usable, non-sterile Foot Control (wired or wireless)
- Sterile, disposable, single-use COBLATION Wand(s)
- Reusable, non-sterile power cord.

The WEREWOLF+ COBLATION System (K210423) is an iteration of WEREWOLF COBLATION system (cleared via 510(k) K192027). The WEREWOLF+ COBLATION System utilizes bipolar technology specifically designed for the resection, ablation, and coagulation of blood vessels in various arthroscopic, orthopedic (cleared via K162074), otorhinolaryngology (ENT) procedures (cleared via K192074), and hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures (cleared via K210423).

The WEREWOLF+ controller is an enclosed unit with incorporated software that runs both the delivery of radiofrequency energy as well as a Graphical User Interface which the user can control various modes, levels, volume, etc. Ports for connecting the compatible Wands and the Foot Control are located on the front panel. An optional wireless Foot Control can be installed. The Controller also incorporates a peristaltic Integrated Fluid Control Module, which provides dynamic control of saline flow (inflow or outflow) to or from the surgical site. The system offers five distinct Modes of Operation (cleared via K162074) for arthroscopic and orthopedic procedures: Hi (Ablation), Med (Ablation), Lo (Ablation), Vac (Vacuum), and COAG (Hemostasis), and four modes for ENT

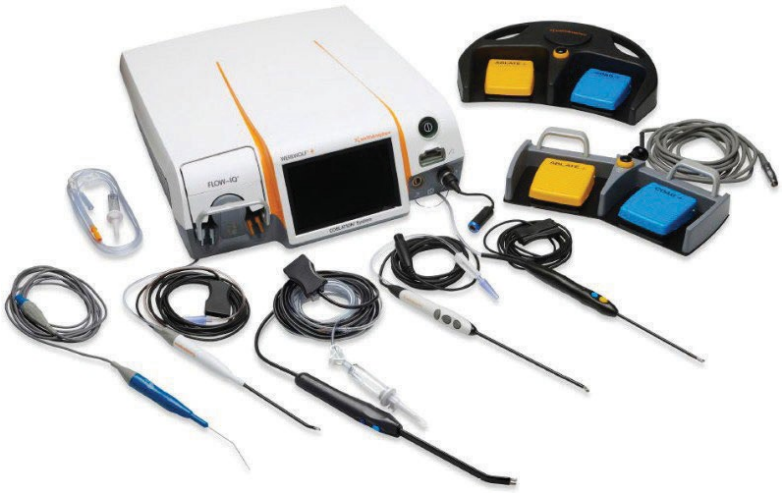

Figure 2 WEREWOLF Coblation System

procedures (cleared via K192027), and one mode (COAG) for hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures (cleared via K210423).

5 INDICATIONS FOR USE

5.1 ARIS COBLATION Turbinate Reduction Wand

The ARIS COBLATION Turbinate Reduction Wand, used with the WEREWOLF COBLATION System, is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage.

6 SUMMARY OF THE TECHNOLOGICAL FEATURES OF SUBJECT DEVICE AND PREDICATE DEVICE SYSTEMS

The subject device (ARIS Wand) and predicate device (ArthroCare Turbinator) are bipolar electrosurgical wands and share the same technological characteristics (i.e., design, similar material, and energy source), intended use, principle of operation and fundamental scientific technology.

As the subject device and predicate device are intended to be used with controllers that generated radiofrequency, the comparison of these wands along with controllers is detailed in the below sections

Table 1 below presents summary of the technological characteristics with exceptions highlighted in ***bold italicized*** font.

Table 1 Comparison Of Technological Characteristics Between The Predicate And Subject Device Systems

Parameter	Predicate Device **ArthroCare Turbinator with WEREWOLF COBLATION System (K202006)**	Subject Device	
		ARIS COBLATION Turbinate Reduction Wand with WEREWOLF COBLATION System (K192027)	**ARIS COBLATION Turbinate Reduction Wand with WEREWOLF+ COBLATION System (K210423)**
Wand Specifications/Features			
Intended use	Indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) sinus surgery involving nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage. The Wand is designed to be used exclusively with the COBLATOR II(CII) controller and Irrigation pump or the WEREWOLF COBLATION system (in conjunction with the ENT adapter and Irrigation Tube Set). Other controllers/pumps must not be used	The ARIS COBLATION Turbinate Reduction Wand, used with the WEREWOLF COBLATION System, is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage.	The ARIS COBLATION Turbinate Reduction Wand, used with the WEREWOLF COBLATION System, is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage.
Wand Materials			
Electrode Materials	Tungsten	Same	Same
Shaft Material and Return electrode material	***304 Stainless steel***	***17-4 stainless steel (Elevator tip) 304 stainless steel***	***17-4 stainless steel (Elevator tip) 304 stainless steel***

		(Return tube)	***(Return tube)***
Return Electrode Insulation	***Polyolefin***	***Pebax extruded tube***	***Pebax extruded tube***
Active electrode Insulation	Polyolefin heat shrink tube	Same	Same
Spacer	99.5% Alumina	Same	Same
Suction/Saline Tubing	***Nylon (internal)/PVC (external)***	***Pebax extruded tube (internal) / PVC (external)***	***Pebax extruded tube (internal) / PVC (external)***
Integrated Suction	Contains Integrated Suction. Colorite 8088G-015		
	0.082 inch ID, 0.155 inch OD	***0.091 inch ID, 0.155 inch OD***	***0.091 inch ID, 0.155 inch OD***
Adhesive	***Epoxy, Cyanoacrylate, UV Adhesive***	***HV-10 heat cure epoxy PN 95389 UV Adhesive***	***HV-10 heat cure epoxy PN 95389UV Adhesive***
Handle/Bushing Material	Polycarbonate	Same	Same
Wand Specifications			
Total Length	85±10mm	85±10mm	85±10mm
Handle Length	4.4 inches	Same	Same
Distal Tip Diameter	***2.9mm***	***2.4mm***	***2.4mm***
Distal Tip Shape	***Blunt Shape***	***Elevator tip***	***Elevator tip***
Number of Electrodes	1 (active) 1 (return)	Same	Same
Number of Internal Suction Channels	1	Same	Same
Materials Biocompatible	Yes	Same	Same
Electrode Configurations	Electrode on one side of wand tip	Same	Same
Wand cable	Integrated cable	Same	Same
Rigid/Flexible Construction	Rigid	Same	Same
Spacer Configuration	Single-Lumen	Same	Same
Suction and/or Irrigation Line	Present	Same	Same
Packaged Sterile	Yes	Same	Same
Single Use Disposable	Yes	Same	Same
Bipolar/Monopolar	Bipolar	Same	Same

Packaged sterile	Yes	Same	Same
Sterilization	***Radiation***	***Ethylene Oxide***	***Ethylene Oxide***
Use limit	***Mechanical use limit (fuse in the handle of the Wand that is blown after the device is connected to the Controller)***	***24-hour life from when wand is first activated (microchip in the handle of the Wand that only allows the Wand to be used for 24 hours after activation)***	***24-hour life from when wand is first activated (microchip in the handle of the Wand that only allows the Wand to be used for 24 hours after activation)***
Cable Assembly – Connector (Does the Wand need Adaptor?)	***WEREWOLF ENT Adaptor is required to connect with WW controller***	***No ENT adaptor required. The Wand comes with a WEREWOLF compatible cable with custom connector and Integrated micro-chip***	***No ENT adaptor required. The Wand comes with a WEREWOLF compatible cable with custom connector and Integrated micro-chip***
Tip Clearing tool	***None***	***Included with device Nitinol wire, .020-inch diameter Polycarbonate handle***	***Included with device Nitinol wire, .020-inch diameter Polycarbonate handle***
Operating life	***1.5 min (1Xlife)***	***2 minutes (1x life) 3 minutes (use limit)***	***2 minutes (1x life) 3 minutes (use limit)***
Saline Source	External Saline Delivery	Same	Same
Electrical safety/EMC	IEC 60601-2-2 compliant	Same	Same
Suction and/or Irrigation	Yes	Same	Same
Tyvek packaging/Adhesive	Yes	Same	Same
Operates in saline environment	Yes	Same	Same
Software in Wand	***No***	***Yes***	***Yes***
Controller Specifications/Features			
Ablation / Resection	Yes	Same	Same
Homeostasis/Coagulation	Yes	Same	Same
Input power	100-120/220-240V	Same	Same
Output Frequency	100 KHz	Same	Same
Fuse Rating	16Amps	16Amps	16Amps
Output Nominal Voltage Maximum	340 Vrms	Same	Same
Rated Wand Voltage	340 Vrms	Same	Same
Default Coblation/Ablation Set Point/Output Voltage (Vrms)	***Set Point 7/265***	***Med • (265 Vrms)***	***Med • (265 Vrms)***

Coblation/Ablation Set Points/Output Voltage (Vrms)	***Set Point 1-9/100-300***	***Lo - to Hi + / 245-280***	***Lo - to Hi + / 245-280***
Default Coagulation Set Point/Output Voltage	***Set Point 3 (75 Vrms)***	***Coag• (66 Vrms at 200 Ohm load)***	***Coag• (66 Vrms at 200 Ohm load)***
Coagulation Set Point / Output	***Set Point 1-5/ 65-87 Vrms***	***66-79 Vrms at 200 Ohm load***	***66-79 Vrms at 200 Ohm load***
Controller wave form	Square wave	Same	Same
Output Control mechanism	Wired or wireless foot pedal	Same	Same
Saline Outflow	Connects to hospital wall suction	Same	Same
Saline Delivery	***Contains integrated saline lumen. PVC Unichem 7077GTX-015, 0.108-inch ID, 0.152-inch OD***	***Contains integrated saline lumen. PVC, Colorite 8088G-015, 0.091-inch ID, 0.155-inch OD***	***Contains integrated saline lumen. PVC, Colorite 8088G-015, 0.091-inch ID, 0.155-inch OD***
	Integrated peristaltic pump (FLOW IQ pump – K192027) on the COBLATION System controls saline delivery to the Wand.	Same	Same
Activation	Foot Control	Same	Same
Software Program	Graphic User Interface (GUI) V 3.0 Main RF controller software V 4.1	Same	Graphic User Interface (GUI) V 5.0 Main RF controller software V 6.1
Graphical User Interface	Yes	Yes	Yes
Weight	10Kg	Same	Same

7 COMPARISON OF SUBJECT AND PREDICATE DEVICES

7.1 WEREWOLF COBLATION Systems

Both the subject systems and the predicate system share same intended use, indications of use, fundamental technology and principle of operation.

The Predicate device ArthroCare Turbinator is intended to be used with WEREWOLF COBLATION System and COBLATOR II controller (via K202006), whereas, the subject device ARIS Wand can be used either with WEREWOLF controller or WEREWOLF+ controller. Both the WEREWOLF controllers share, same fundamental technology, and principle of operation when used for ENT procedures.

There are no technological (hardware or software) changes made to the controllers (WEREWOLF COBLATION System, WEREWOLF+ COBLATION System were cleared previously via K192027 and K210423 respectively) to be compatible with ARIS wand.

Output Voltage Settings: As identified in the Table 1 above, the output voltage settings (Coblation, Ablation and coagulation) in the controllers, for the use with ARIS Wand have been made specific to simplify setting selection.

Software Program: There were no changes required to WEREWOLF software as part of this submission. The previously cleared versions of the WEREWOLF COBLATION System referenced in this submission have already undergone all required testing to support use of ENT Wands. Please see K192027, and K210423 for all required software documentation

7.2 ARIS COBLATION Turbinate Reduction Wand

The differences in technological characteristics for ARIS wand and ArthroCare Turbinator wand are summarized in table below and highlighted in ***italics.***

The technological differences include wand software, smaller distal tip diameter, elevated distal tip, tip clearing tool in ARIS Wand. There are differences in materials used for return electrode, suction line tubing, along with sterilization methods used, and these changes are made to ensure manufacturability and logistical flexibility.

Table.2 Comparison Of Technological Characteristics Of Turbinator Wand And ARIS Wand

Parameter	**Predicate Device** **ArthroCare Turbinator Wand**	**Subject Device** **ARIS Wand**
Controller Used	WW COBLATION SYSTEM (WW ENT Controller) or COBLATOR II Controller	WW COBLATION SYSTEM (WW ENT Controller) or WW+ COBLATION SYSTEM
Intended use	Indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) sinus surgery involving nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage. The Wand is designed to be used exclusively with the COBLATOR II (CII) controller and Irrigation pump or the WEREWOLF COBLATION System (in conjunction with the ENT Adapter and Irrigation Tube Set). Other controllers/pumps must not be used.	The ARIS COBLATION Turbinate Reduction Wand, used with the WEREWOLF COBLATION System, is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: nasal airway obstruction by reduction of hypertrophic nasal turbinates and submucosal tissue shrinkage.
Wand Materials		
Electrode Materials	Tungsten	Same
Spacer	99.5% Alumina	Same
Adhesive	***Epoxy, Cyanoacrylate, UV Adhesive***	***HV-10 heat cure epoxy*** ***PN 95389*** ***UV Adhesive***
Shaft Materials	***Stainless Steel (SS304)***	***Stainless Steel (SS304, SS17-4)***
Suction/Saline Tubing	***Nylon (internal)***/PVC (external)	***Pebax extruded tube (internal)*** / PVC (external)
Return electrode Material	***304 Stainless steel***	***17-4 stainless steel*** ***(Elevator tip)*** ***304 stainless steel*** ***(Return tube)***
Active electrode Insulation	Polyolefin heat shrink tube	Same
Return Electrode Insulation	***Polyolefin***	***Pebax extruded tube***
Handle/Bushing Material	Polycarbonate	Same
Integrated Suction	Contains Integrated Suction. Colorite 8088G-015	
	0.082 inch ID, 0.155 inch OD	***0.091 inch ID, 0.155 inch OD***
Wand Specifications		

Total Length	85±10mm	85±10mm
Handle Length	4.4 inches	Same
Distal Tip Diameter	***2.9mm***	***2.4mm***
Distal Tip Shape	***Blunt Shape***	***Elevator tip***
Number of Electrodes	1 (active) 1 (return)	Same
Number of Internal Suction Channels	1	Same
Materials Biocompatible	Yes	Same
Electrode Configurations	Electrode on one side of wand tip	Same
Wand cable	Integrated cable	Same
Rigid/Flexible Construction	Rigid	Same
Spacer Configuration	Single-Lumen	Same
Suction and/or Irrigation Line	Present	Same
Packaged Sterile	Yes	Same
Single Use Disposable	Yes	Same
Bipolar/Monopolar	Bipolar	Same
Sterilization	***Radiation***	***Ethylene Oxide***
Use limit	***Mechanical use limit (fuse in the handle of the Wand that is blown after the device is connected to the Controller)***	***24-hour life from when wand is first activated (microchip in the handle of the Wand that only allows the Wand to be used for 24 hours after activation)***
Cable Assembly - Connector	***WEREWOLF ENT Adaptor is required to connect with WW controller***	***No ENT adaptor required. The Wand comes with a WEREWOLF compatible cable with custom connector and Integrated micro-chip***
Tip Clearing tool	***None***	***Included with device Nitinol wire, .020-inch diameter Polycarbonate handle***
Operating life	***1.5 min (1Xlife)***	***2 minutes (1x life) 3 minutes (use limit)***
Saline Source	External Saline Delivery	Same
Electrical safety/EMC	IEC 60601-2-2 compliant	Same
Suction and/or Irrigation	Yes	Same

Tyvek packaging/Adhesive	Yes	Same
Operates in saline environment	Yes	Same
Software in Wand	***No***	***Yes***

8. PERFORMANCE TESTING – NON CLINICAL

For the non-clinical performance testing, either of WW controller were selected as representative model for the Werewolf coblation systems, as both the controllers have ENT functionality in common. The functional tests performed on the ARIS wand included:

1.Coagulation performance
2.Ablation performance
3.Active life
4.Suction performance
5.Tip clearing component functionality
6.Mechanical testing
7.EMC testing
8.Functional tests

Based on the bench testing, the ARIS Wand was found to meet all performance specifications.

9. PERFORMANCE TESTING – PRE-CLINICAL

Pre-clinical (ex vivo) testing was conducted on the on a bovine myocardial tissue model using predicate (ArthroCare Turbinator Wand) and the subject device, ARIS Wand. The insertion channel diameters, thermal zone areas, and thermal zone volumes of the Aris Wand were substantially equivalent to the predicate Turbinator Wand in both the ablation and coagulation settings.

10. PERFORMANCE TESTING – ADDITIONAL

Additional bench testing was performed to compare the peak temperature at the active electrode of the proposed ARIS Wand to the predicate ArthroCare Turbinaor Wand after 10 seconds of activation at maximum setting. The maximum temperatures recorded for the ARIS device were lower than the Turbinator Wand. Average peak temperatures for the wands were in the range of 50-67°C.

11. PERFORMANCE TESTING – ANIMAL

No animal testing was performed on this product.

12.0 PERFORMANCE TESTING – CLINICAL

No clinical data are included in this submission.

13.0 STERILIZATION:

The ARIS Wand is sterilized utilizing 100% Etyhlene Oxide (Eto or EO) gas via an existing validated EO Cycle. The evaluation and adoption are based on the principles outlined in AAMI TIR 28:2016. The sterilization method ensures a minimum sterility assurance level of 10^{-6}

14. SHELF LIFE:

Shelf life testing included environmental conditioning (T=0), transit conditioning, accelerated aging studies at T=8 months, packaging integrity testing - visual inspection of seal, gross leak (bubble emission), dye penetration, peel strength testing, and delamination.

15. PACKAGING:

The ARIS Wand is supplied sterile and is intended for single use only. The Wand is not cleaned or re-sterilised for re-use. All packaging has been validated in accordance with ASTM D4332:2014, ASTM D4169:2016, ISO 11607-1:2019 and ISO 11607-2:2019.

The WEREWOLF Controllers are supplied non-sterile and are reusable; cleaning measures are provided in the manual. There were no changes to the Controller that required packaging testing to be repeated for this 510(k) submission.

16. BIOCOMPATIBILITY:

ARIS Wand is classified as an externally communicating medical device with tissue/bone/dentin contact with limited duration (≤24 h) per ISO 10993-1:2018. The subject Wand met the acceptance criteria under the conditions of the chemical characterization and biological testing performed.

WEREWOLF Controller does not require biocompatibility testing as the Controller has no direct or indirect patient-contacting materials.

17. Electrical safety and electromagnetic compatibility Testing

The subject device complies with IEC60601-1:2005+A1:2012, IEC60601-2-2:2017, IEC 60601-1-6: 2010 Ed.3+A1 standards for safety and the IEC 60601-1-2:2014 standard for EMC.

18. Software verification and Validation testing

The ARIS Wand software (version 4.8) is identical to the wand software cleared via K183346 (FLOW 90). The software for the subject devices was considered as a "moderate" level of concern and software verification and validation testing conducted in accordance to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The overall software architecture for the WEREWOLF Controllers is the same as the previously cleared WEREWOLF Controller (K192027) and WEREWOLF+ Controller (K210423).

19. CYBERSECURITY

The ARIS Wand software (version 4.8) is identical to the wand software cleared via K183346 (FLOW 90). The Cyber Failure Modes and Effects Analysis (CMEA) confirms that that there are no known unacceptable cybersecurity hazards when ARIS Wand is used with the WEREWOLF COBLATION Systems.

20. CONCLUSION

All testing demonstrates that the ARIS COBLATION Turbinate Reduction Wand performs as intended and has acceptable performance when used with WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423) in accordance with its labeling. As hardware and software supporting ENT functionality are identical across the controllers used with the subject device, the performance testing results are representative of ARIS Wand with

WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423).

The software in ARIS Wand is identical to the reference predicate FLOW 90 (K183346). As the intended use, principle of operation and fundamental scientific technology are equivalent to the predicate device system (TURBINATOR Wand with WEREWOLF COBLATION System), the subject device system, (ARIS Wand used with WEREWOLF COBLATION systems) is as safe and effective as the predicate device.