December 20, 2019

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

Re: K192027
Trade/Device Name: WEREWOLF COBLATION System, COBLATION HALO 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 18, 2019
Received: November 19, 2019

Dear Shruthi 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/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,

Long Chen, Ph.D.
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

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)*
K192027

Device Name
WEREWOLF™COBLATION™ SYSTEM
COBLATION™ HALO™ WAND

Indications for Use *(Describe)*
Indications for Use - WEREWOLF™COBLATION™ SYSTEM

The WEREWOLF COBLATION System controller is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following otorhinolaryngology (ENT) procedures:
Resection/Ablation/Coagulation
- Tonsillectomy (Including Palatine Tonsils)
- Adenoidectomy
- Uvulopalatopharyngoplasty (UPPP)
- Traditional Uvulopalatoplasty (RAUP)
- Nasal Airway Obstruction
- Submucosal Palatal Shrinkage
- Submucosal Tissue Shrinkage
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Reduction of Turbinates for the Treatment of Nasal Airway Obstruction
- Nasopharyngeal/Laryngeal Indications Including Tracheal Procedures
- Mastoidectomy
- Myringotomy with Effective Hemorrhage Control
- Papilloma Keloids
- Nasopharyngeal/Laryngeal Procedures
- Polypectomy
- Laryngeal Polypectomy
- Laryngeal Lesion Debulking
- Cysts
- Tumors
- Neck Mass
- Head, Neck, Oral, and Sinus Surgery
- Tissue in the Uvula/ Soft Palate for the Treatment of Snoring

Indications for use – COBLATION™ HALO™ Wand

The COBLATION HALO 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: tonsillectomy, adenoidectomy, and uvulopalatopharyngoplasty (UPPP). It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate.

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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# 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.

## 7.1 GENERAL INFORMATION


| | |
|---|---|
| **Submitter Name** | ArthroCare Corporation |
| **Address** | 7000 West William Cannon Drive<br>Austin, TX 78735 |
| **Contact Person** | Shruthi Bhat M.Sc., MS<br>Regulatory Affairs Specialist II<br>Arthrocare Corporation<br>7000 West William Cannon Drive<br>Austin, TX 78735<br>**Phone:** (512) 895-1295<br>**Email:** shruthi.bhat@smith-nephew.com<br>**Fax:** 512-895-1489 |
| **Date Prepared** | 20 December 2019 |


## 7.2 DEVICE NAME(S)

| | |
|---|---|
| **Proprietary Name** | WEREWOLF™COBLATION™ SYSTEM<br>COBLATION™ HALO™ 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 |

**7.3 PREDICATE DEVICE(S)** ARTHROCARE ENT COBLATOR II SURGERY SYSTEM cleared via K030108

PROCISE XP Wand cleared via K070374

## 7.4 DESCRIPTION

### 7.4.1 WEREWOLF™ (RF20000) COBLATION™ System

The proposed 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 components are designed to be operated as a single unit.

The WEREWOLF COBLATION System utilizes bipolar technology specifically designed for the resection, ablation, and coagulation of tissues and hemostasis of blood vessels in various arthroscopic, orthopedic and otorhinolaryngology (ENT) procedures.

### 7.4.2 WEREWOLF™ (RF20000) Controller

The proposed Controller is designed to deliver radiofrequency energy to the electrodes of the compatible COBLATION Wand. The Controller is an enclosed unit with incorporated software that runs both the delivery of radiofrequency energy as well as a Graphical User Interface with 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 proposed Controller operates in 5 modes (Lo, Med, Hi, Coag and Vac mode) for arthroscopic and orthopedic procedures and in 4 modes (Lo, Med, Hi and Coag) for the ENT procedures.

### 7.4.3 COBLATION™ HALO™ Wand

The proposed HALO Wand is designed to be used exclusively with the proposed WEREWOLF™ COBLATION™ System. The HALO Wand is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: tonsillectomy, adenoidectomy, and uvulopalatopharyngoplasty (UPPP). It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate. The Wands are provided sterile (via ethylene oxide) and are single-use only.

## 7.5 PROPOSED INTENDED USE/INDICATIONS FOR USE

### 7.5.1 WEREWOLF COBLATION System

The proposed WEREWOLF COBLATION System controller is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following otorhinolaryngology (ENT) procedures:

| | **Resection/Ablation/Coagulation** |
|---|---|
| **ENT** | ▪ Tonsillectomy (Including Palatine Tonsils)<br>▪ Adenoidectomy<br>▪ Uvulopalatopharyngoplasty (UPPP)<br>▪ Traditional Uvulopalatoplasty (RAUP) |

| | Resection/Ablation/Coagulation |
|---|---|
| | ▪ Nasal Airway Obstruction<br>▪ Submucosal Palatal Shrinkage<br>▪ Submucosal Tissue Shrinkage<br>▪ Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates<br>▪ Reduction of Turbinates for the Treatment of Nasal Airway Obstruction<br>▪ Nasopharyngeal/Laryngeal Indications Including Tracheal Procedures<br>▪ Mastoidectomy<br>▪ Myringotomy with Effective Hemorrhage Control<br>▪ Papilloma Keloids<br>▪ Nasopharyngeal/Laryngeal Procedures<br>▪ Polypectomy<br>▪ Laryngeal Polypectomy<br>▪ Laryngeal Lesion Debulking<br>▪ Cysts<br>▪ Tumors<br>▪ Neck Mass<br>▪ Head, Neck, Oral, and Sinus Surgery<br>▪ Tissue in the Uvula/ Soft Palate for the Treatment of Snoring |

### 7.5.2 COBLATION HALO Wand

The COBLATION HALO 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: tonsillectomy, adenoidectomy, and uvulopalatopharyngoplasty (UPPP). It is intended for procedures using a conductive media, such as normal saline or Ringer's lactate.

## 7.6 SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

The overall technological characteristics of the proposed devices are the same as the predicate devices with exceptions listed in Table 7.6. The proposed and predicate controller differ in controller specifications due to different controller hardware design, software design and, multiple applications.

**Table 7.6: Summary of Technological Characteristics between the predicate and proposed devices.**

| **Parameter** | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Representation |  |  |
| Intended Use and Indications of Use | Indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) procedures | Same |
| Otorhinolaryngology (ENT) procedures | ▪ Tonsillectomy (Including Palatine Tonsils)<br>▪ Adenoidectomy<br>▪ Uvulopalatopharyngoplasty (UPPP)<br>▪ Traditional Uvulopalatoplasty (RAUP)<br>▪ Nasal Airway Obstruction<br>▪ Submucosal Palatal Shrinkage<br>▪ Submucosal Tissue Shrinkage | Same |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| | ▪ Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates<br>▪ Reduction of Turbinates for the Treatment of Nasal Airway Obstruction<br>▪ Nasopharyngeal/Laryngeal Indications Including Tracheal Procedures<br>▪ Mastoidectomy<br>▪ Myringotomy with Effective Hemorrhage Control<br>▪ Papilloma Keloids<br>▪ Nasopharyngeal/Laryngeal Procedures<br>▪ Polypectomy<br>▪ Laryngeal Polypectomy<br>▪ Laryngeal Lesion Debulking<br>▪ Cysts<br>▪ Tumors<br>▪ Neck Mass<br>▪ Head, Neck, Oral, and Sinus Surgery<br>▪ Tissue in the Uvula/ Soft Palate for the Treatment of Snoring<br>▪ | |
| Input power | 100-240 VAC | Same |
| Frequency | 50-60 Hz | Same |
| Fuse Rating | 5 Amps | **16 Amps** |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Output Nominal Voltage Maximum | 320±10% Vrms | **340 Vrms** |
| Controller input power (W) | 100-120V ~ 8A 220-240V ~ 4A | Same |
| Rated Wand Voltage | 320±10% Vrms | **340 Vrms** |
| Default Ablation Set Point / Output Voltage (Vrms) | Set Point 7 (265 Vrms) | **"Med•" (175 Vrms)** |
| Default Coagulation Set Point / Output Voltage (Vrms) | Set Point 3 (75 Vrms) | **"Coag•" (73 Vrms at 150 Ohm Load)** |
| Ablation Set Point Range / Output Voltage (Vrms) | Set Points 1 - 9 (100-300 Vrms) | **"Med –" - "Hi +" (167-300 Vrms)** |
| Coagulation Set Point Range / Output Voltage (Vrms) | Set Points 1 - 5 (65-87 Vrms) | **"Coag •" – "Coag •••" (73-99 Vrms at 150 Ohm Load)** |
| Coagulation Setting | Adjustable (5 Set Points) | **Adjustable (3 Set Points)** |
| Controller wave form | Square | Same |
| Output Frequency | 100kHz | Same |
| Saline Outflow | Connects to hospital wall suction | Same |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Saline Delivery | External Flow Control Unit of the Controller controls gravity supplied saline to the wand. | **Integrated peristaltic pump (FLOW IQ pump - K143235 and K162074) on the Controller controls saline delivery to the Wand** |
| Activation | Foot Control | Same |
| Software controlled | No | **Yes** |
| Graphical User Interface | No | **Yes** |
| Weight | 8.2kg | **10 kg** |
| Total Length | 9.1 inches | **9.0 inches** |
| Handle Length | 4.4 inches | Same |
| Shaft Materials | ASTM A908 Grade 304 Stainless Steel | Same |
| Shaft Working Length | 4.6 inches | Same |
| Rigid Construction | Yes | Yes |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Distal Tip Configuration |   |   |
| Electrode Material | Molybdenum | **Tungsten Alloy** |
| Active Electrode Configuration | Three (3) Molybdenum wire electrodes | **One (1) Tungsten alloy electrode** |
| Electrode Orientation relative to Shaft | 23° | **25**° |
| Outer Diameter of Shaft | 4.57 mm (Insulated) | **4.09 mm x 5.03 mm (Obround Shaft, Insulated)** |
| Number of Suction Ports | 1 | Same |
| Electrode Dimensions | Width: 3.00 mm<br>Length:1.55 mm<br>Thickness:0.41 mm | **Width: 3.45 mm**<br>**Length:4.04 mm**<br>**Thickness: 0.30 mm** |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Recommended Active Ablation Time | 10 minutes of cumulative ablation (1X life) | **15 minutes of cumulative ablation (1X life)** |
| Electrode | Molybdenum | **Tungsten alloy** |
| Ceramic Spacer | Alumina | Same |
| Shaft | Grade 304 Stainless Steel | Same |
| Shaft Insulation | Black Polyolefin | Same |
| Wire Insulation | Pebax (7033-SA01/MED) | Same |
| Shaft Support Component | N/A | **Grade 302 Stainless Steel** |
| Adhesive(s) | Loctite 3981, Loctite Accelerator 713, Loctite 4013 , UV Adhesive, Loctite 3321, PVC Solvent Cement | **HV-10 Heat-Cure Adhesive, Cyberbond Cyanoacrylate, Cyberbond Accelerator,** PVC Solvent Cement, Loctite 3321 |
| Saline/ Suction Tubing | PVC (does not contain DEHP), ABS, HDPE | PVC (does not contain DEHP), ABS, **Nylon 12** |

| Parameter | **PREDICATE DEVICE**: Procise XP (K070374) with COBLATOR II Controller (K030108) | **PROPOSED DEVICE**: HALO with WEREWOLF Controller |
|---|---|---|
| Handle Bushing | Polycarbonate | Same |
| Bipolar/ Monopolar | Bipolar | Same |
| Spacer Configuration | Multi-lumen | Same |
| Irrigation Ports | 3 | **5** |
| Activation Method | Foot Pedal | Same |
| Software in Wand | No | **Yes** |
| Use-limiting Feature | No | **Yes – Software Controlled** |
| Integrated Cable | Yes | Yes |
| Biocompatible | Yes | Yes |
| Sterilization | Irradiation | **Ethylene Oxide** |
| Packaged Sterile/ Single Use Disposable | Sterile, Single Use, Disposable | Same |

## 7.7 PERFORMANCE TESTING

Performance testing to assess the design and performance was conducted on the proposed devices, the HALO Wand (Wand) with WEREWOLF Controller (Controller) to confirm the proposed devices meet the established design criteria and supports the substantial equivalence with the predicate devices, PROCISE XP wand (K070374) and COBLATOR II Controller (K030108). Testing included:

- **Non-Clinical Testing:**
  - ***Mechanical Tests*** - distal tip mechanical tests, tip clearing accessory insertion and removal force, integrated cable plug insertion and extraction, and cable and saline tube mechanical integrity
  - ***Electrical Tests*** - electrical continuity, dielectric withstand, electrical impedance, overcurrent, and electrical safety per IEC 60601-1 and IEC 60601-2-2
  - ***Functional Tests*** - transit conditioning, gloved surfaces testing, dimensional inspection, visual inspection, suction clog resistance and blockage removal, suction and saline rate testing, pinch clamp occlusion testing, coagulation effect, ablation function in all settings, ablation and device function at 1X and 2X life, device use-limiting check, wand software usage information check, device shutoff timer check, and maximum temperature check, software verification and validation, biocompatibility

- **Pre-Clinical bench testing (ex vivo testing):**

  Evidence obtained from preclinical bench tissue testing (ex vivo) on bovine myocardial tissue demonstrates that the HALO device performs substantially equivalent to the PROCISE XP predicate device in relevant aspects associated with Ablation mode and Coagulation mode thermal effects.

- **Additional Bench Testing**

  Additional bench testing was performed to compare the peak temperature at the active electrode of the proposed HALO Wand to the predicate PROCISE XP wand after 10 seconds of activation at maximum setting. The maximum temperatures recorded for the devices ranged from approximately 61.4 - 74.3°C.

## 7.8 PERFORMANCE TESTING – ANIMAL

No in vivo animal testing data are included in this submission.

## 7.9 PERFORMANCE TESTING - CLINICAL

No clinical data are included in this submission.

## 7.10 CONCLUSION

All testing demonstrates that the proposed WEREWOLF Controller and the HALO 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 the proposed devices are substantially equivalent to the predicate devices for their intended use, principle for operation and fundamental scientific technology.