December 18, 2020

ArthroCare Corporation
Jean Asquith
Senior Regulatory Affairs Specialist
7000 West William Cannon Drive, Building One
Austin, Texas 78749

Re: K202006
Trade/Device Name: ENT Plasma Wands, Turbinator Wand, Werewolf Irrigation Tube Set, Werewolf ENT Adapter, Werewolf Coblation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 20, 2020
Received: November 19, 2020

Dear Jean Asquith:

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)*
K202006

Device Name
ENT Plasma Wands and Turbinator Wands

Indications for Use *(Describe)*

Subject Device(s) Indications of Use
ENT Wands
ENT Plasma Wands
Indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: adenoidectomy, cysts, head, neck, oral, and sinus surgery, mastoidectomy, myringotomy with effective hemorrhage control, nasal airway obstruction by reduction of hypertrophic nasal turbinates, nasopharyngeal/ laryngeal indications including tracheal procedures, laryngeal polypectomy, and laryngeal lesion debulking, neck mass, papilloma keloids, submucosal palatal shrinkage, submucosal tissue shrinkage, tonsillectomy (including palatine tonsils), traditional uvulopalatoplasty (RAUP), tumors, and tissue in the uvula/soft palate for the treatment of snoring.

Turbinator Wands
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.

-Continued-

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.

Accessories

WEREWOLF ENT Adapter

The WEREWOLF ENT Adapter, in conjunction with the Smith & Nephew COBLATOR II Compatible ENT Wands, the Smith & Nephew WEREWOLF COBLATION System and the WEREWOLF Irrigation Tube Set (as needed) are indicated for the ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in ENT/otorhinolaryngology procedures.

WEREWOLF Irrigation Tube Set

The WEREWOLF Irrigation Tube Set, in conjunction with the Smith & Nephew COBLATOR II Compatible ENT Wands, the Smith & Nephew WEREWOLF COBLATION System and the WEREWOLF ENT Adapter are indicated for the ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in ENT/otorhinolaryngology procedures.

510(k) Summary
ArthroCare® Corporation

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

ArthroCare® Corporation
7000 W. William Cannon Drive
Building One
Austin, TX 78735

Company Contact:	Jean Asquith Tel: (512) 680-5802 Fax: (512) 895-1489
Email:	jean.asquith@smith-nephew.com

Date Prepared:	December 18, 2020

2. DEVICE IDENTIFICATION

Device Trade Name:	ENT Plasma Wands, Turbinator Wand, Werewolf Irrigation Tube Set, Werewolf ENT Adapter, Werewolf Coblation System
Device Common Name:	Electrosurgical Devices and Accessories
Regulation Number:	21 CFR 878.4400
Regulation Description:	Electrosurgical Cutting and Coagulation Devices and Accessories
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery
Predicate Device:	ENT Plasma Wands (K070374 – February 7, 2007 and K142999 – Nov 19, 2014) and Turbinator Wand (K122652- July 02, 2013) used with the ENT Coblator Surgery System (K030108 – Feb 03, 2003)

3. DEVICE DESCRIPTION

The ENT Plasma Wands (K070374 and K142999) and Turbinator Wand (K122652) are currently cleared to be used with the ArthroCare ENT Coblator Surgery System (COBLATOR II) (K030108). This 510(k) is to obtain clearance for the use of ENT Wands, in conjunction with two accessories, with the recently cleared WEREWOLF COBLATION System (K192027 - Dec 20, 2019). The accessories are the WEREWOLF ENT Adapter and the WEREWOLF Irrigation Tube Set The extended compatibility does

not result in any changes to the overall design or to the indications of use for the ENT Wands nor the WEREWOLF COBLATION System.

ENT Plasma Wands are bipolar, single use, high frequency electrosurgical devices designed for use in ablation, resection and coagulation of soft tissue, and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery.

Turbinator Wand is a bipolar, single use, high frequency electrosurgical device designed for use for specific turbinate indications in otorhinolaryngology (ENT) procedures.

The **WEREWOLF ENT Adapter** is a reusable, electrically-activated adapter with an 8-pin connector at the distal end and an 18-pin connector at the proximal end. The reusable WEREWOLF ENT Adapter is designed to be used with the COBLATOR II Compatible ENT Wands (8-pin connector) and WEREWOLF COBLATION System (18-pin connector), along with the WEREWOLF Irrigation Tube Set, as needed.

The **WEREWOLF Irrigation Tube Set** is a single use, disposable, sterile device. The Irrigation Tube Set is designed to be used with COBLATOR II compatible ENT Wands and WEREWOLF COBLATION System, along with the reusable WEREWOLF ENT Adapter. The spike of the Irrigation Tube Set is connected to an irrigation source for select ENT Wands; that is, the ENT wands that use a conductive media, such as normal saline intraoperatively.

4. INDICATIONS FOR USE

Subject Device(s)	Indications of Use
ENT Wands	
ENT Plasma Wands	Indicated for ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including: adenoidectomy, cysts, head, neck, oral, and sinus surgery, mastoidectomy, myringotomy with effective hemorrhage control, nasal airway obstruction by reduction of hypertrophic nasal turbinates, nasopharyngeal/laryngeal indications including tracheal procedures, laryngeal polypectomy, and laryngeal lesion debulking, neck mass, papilloma keloids, submucosal palatal shrinkage, submucosal tissue shrinkage, tonsillectomy (including palatine tonsils), traditional uvulopalatoplasty (RAUP), tumors, and tissue in the uvula/soft palate for the treatment of snoring.

Subject Device(s)	Indications of Use
ENT Wands	
Turbinator Wands	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.
Accessories	
WEREWOLF ENT Adapter	The WEREWOLF ENT Adapter, in conjunction with the Smith & Nephew COBLATOR II Compatible ENT Wands, the Smith & Nephew WEREWOLF COBLATION System and the WEREWOLF Irrigation Tube Set (as needed) are indicated for the ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in ENT/otorhinolaryngology procedures.
WEREWOLF Irrigation Tube Set	The WEREWOLF Irrigation Tube Set, in conjunction with the Smith & Nephew COBLATOR II Compatible ENT Wands, the Smith & Nephew WEREWOLF COBLATION System and the WEREWOLF ENT Adapter are indicated for the ablation, resection, and coagulation of soft tissue and hemostasis of blood vessels in ENT/otorhinolaryngology procedures

5. 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 1.

Table 1: Summary of Comparison of the Technological Features of Subject and Predicate Devices

Parameter	**PREDICATE DEVICE(S)**: Wands: **ENT Wands** (K070374, K142999 and K122652) + COBLATION System: COBLATOR II COBLATION System (K030108)	**SUBJECT DEVICE(S)**: Wands: **ENT Wands** (K070374, K142999 and K122652)+ Accessories (ENT Adapter + Irrigation Tube Set) + COBLATION System: WEREWOLF COBLATION System (K192027)
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
Input power	100-240 VAC	Same
Frequency	50-60 Hz	Same
Fuse Rating	8 Amps	16 Amps
Output Nominal Voltage Maximum	320±10% Vrms	340 Vrms
COBLATION System input power	100-120V ~ 8A 220-240V ~ 4A	Same
Rated Wand Voltage	320±10% Vrms	Same
Default Ablation Set Point / Output Voltage	Set Point 7 (265 Vrms)	Same
Default Coagulation Set Point / Output Voltage	Set Point 3 (75 Vrms)	Same
Ablation Set Point Range / Output Voltage	Set Points 1 - 9 (100-300 Vrms)	Set Points 0 - 9 (0-300 Vrms)

Parameter	**PREDICATE DEVICE(S)**: Wands: **ENT Wands** (K070374, K142999 and K122652) + COBLATION System: COBLATOR II COBLATION System (K030108)	**SUBJECT DEVICE(S)**: Wands: **ENT Wands** (K070374, K142999 and K122652)+ Accessories (ENT Adapter + Irrigation Tube Set) + COBLATION System: WEREWOLF COBLATION System (K192027)
Coagulation Set Point Range / Output Voltage	Set Points 1 - 5 (65-87 Vrms)	Same
Coagulation Setting	Adjustable (5 Set Points)	Same
COBLATION System wave form	Square	Same
Output Frequency	100kHz	Same
Suction	Connects to hospital suction system	Same
Saline Delivery	External Flow Control Unit used with the COBLATION System supplies saline to the wand.	Integrated peristaltic pump (FLOW IQ pump – K192027) on the COBLATION System controls saline delivery to the wand.
Activation	Foot Control	Same
Software controlled	No	Yes
Software Version	N/A	Main 4.1 and GUI 3.0
Graphical User Interface	No	Yes
Weight	8.2kg	10 kg

6. COMPARISON TO PREDICATE DEVICES

The ENT Wands with the accessories (subject) when used in conjunction with the WEREWOLF COBLATION System are substantially equivalent to the ENT Wands when used with ENT Coblator Surgery System (predicate devices).

The intended use, indications of use, fundamental technology and principle of operation of the subject devices are same as the predicate devices with exceptions including: 1. Compatibility of the subject device wands with the WEREWOLF COBLATION System; 2. Touch-controlled Graphical User Interface (GUI); 3. Integration of software to the WEREWOLF COBLATION System for controlling the wands; and 4. Integrated fluid control module for saline delivery.

7. STERILIZATION

The sterilization nor the shelf life has changed for the ENT wands since the 510(k) clearances. All legacy ENT Wands are still sterilized using radiation with a minimum sterilization assurance level (SAL) of 10^{-6}.

The ENT Adapter and WEREWOLF Controller are supplied non-sterile and reusable. Cleaning measures are provided in the IFU and manual, respectively.

The Irrigation Tube Set is sterilized utilizing 100% Ethylene Oxide (EtO) gas via an existing validated EtO Cycle. The sterilization method ensures a minimum sterility assurance level of 10^{-6}.

8. BIOCOMAPTIBILITY

There is no change in the materials used to manufacture the ENT Wands. Therefore, biocompatibility testing of the ENT Wands was not required for this 510(k) submission.

The ENT Adapter and the WEREWOLF Controller are non-patient contacting; therefore, biocompatibility testing was not required for this 510(k) submission.

The Irrigation Tube Set has indirect patient contact and is classified as an external communicating medical device with tissue/bone/dentin with indirect blood contact with limited duration (<24 h) per ISO 10993-1:2018. Biocompatibility testing was leveraged from the recently cleared HALO Wand (K192027), which met the requirements for ISO 10993-1:2018 for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, materials mediated pyrogenicity, and hemocompatibility

9. SOFTWARE

The software for the WEREWOLF Controller, in conjunction with the ENT Adapter, was designed to control performance for intended use. The software version is Main 4.1 and

GUI 3.0. A Graphical User Interface is utilized for the advancement of technology and to simplify system performance.

10. PERFORMANCE TESTING

Non-clinical performance testing:
Non-clinical performance testing of the ENT Wands with the accessories used in conjunction with the WEREWOLF COBLATION System verified that the subject devices met the established design criteria and supported substantial equivalence with the predicate devices, ENT Wands in conjunction with COBLATOR II System. It included design verification testing, consisting of electrical and mechanical/functional testing, which verified that the design meets the performance specifications. Pre-clinical ex-vivo bench testing was conducted to assess ablation and coagulation mode thermal effects, as well as suction, on bovine myocardial tissue, which verified that the subject devices performed substantially equivalent to the predicate devices.

Neither “Performance Testing – Animal” nor “Performance Testing – Clinical” was conducted to support this 510(k).

11. CONCLUSION

All testing demonstrated that the ENT Wands in conjunction with the accessories perform as intended and have 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 devices to demonstrate that they are substantially equivalent to the predicate devices for their intended use, principle for operation and fundamental scientific technology.