September 1, 2022

Arthrocare Corporation
Alexander Brankner
International Regulatory Affairs Manager
7000 West William Cannon Drive
Building One
Austin, Texas 78735

Re: K220563
Trade/Device Name: Ambient HipVac 50 Wand with Integrated Finger Switches, RF20000 COBLATION System, WEREWOLF COBLATION System, 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 29, 2022
Received: August 1, 2022

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 (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,

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

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.

510(k) Number *(if known)*
K220563

Device Name
Ambient HipVac 50 Wand with Integrated Finger Switches w/ RF20000 Coblation System, WEREWOLF Coblation System and WEREWOLF+ Coblation System.

Indications for Use *(Describe)*
The Ambient HipVac 50 Wand with Integrated Finger Switches is indicated for the resection and ablation of soft tissue, and hemostasis of blood vessels less than 1 mm (via coagulation) 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	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoidale Labrum
Wrist		▪ Triangular Fibrocartilage (TFCC)

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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Section 7 - 510(k) Summary

ArthroCare® Corporation

Ambient HipVac 50 Wand with Integrated Finger Switches 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.

7.1 GENERAL INFORMATION

Submitter Name ArthroCare Corporation

Address 7000 West William Cannon Drive
Austin, TX 78735

Contact Person Alexander Brankner
International Regulatory Affairs Manager
Phone: 512-673-3090
Email: Alexander.Brankner@smith_nephew.com

Date Prepared August 31, 2022

7.2 DEVICE NAME(S)

Subject Device Proprietary Name

Ambient HipVac 50 Wand with Integrated Finger Switches **and**
RF20000 COBLATION System
WEREWOLF COBLATION System
WEREWOLF+ COBLATION System

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)

Ambient HipVac 50 Wand with Integrated Finger Switches	K161481
ArthroCare System 12000 (Quantum II)	K082666

Note: The Ambient HipVac 50 Wand with Integrated Finger Switches may be identified as Ambient HipVac 50 wand.

Note: ArthroCare System 12000 may be identified as QUANTUM II.

Note: The RF20000 COBLATION System (K162074), WEREWOLF COBLATION System (K192027), and the WEREWOLF+ COBLATION system (K210423) collectively may be identified as WEREWOLF COBLATION Systems.

7.4 DEVICE DESCRIPTION

7.4.1 Ambient HipVac 50 Wand with Integrated Finger Switches

The Ambient HipVac 50 Wand is a bipolar, high frequency (HF) electrosurgical device designed for resection and ablation of soft tissue, and hemostasis of blood vessels less than 1 mm (via coagulation) in the indicated arthroscopic and orthopedic procedures (K161481).

The Ambient HipVac 50 Wand consist of a handle, shaft, integrated cable, and suction tubing. The integrated cable and suction tubing are attached to the proximal end of the handle and connect to the Controller and hospital wall suction, respectively. The plastic molded handle includes three integrated finger switches (IFS) used to activate and adjust the Coblation (ablation) and Coagulation modes: CUT (ablation), COAG (coagulation), and set point adjustment. The Ambient feature provides accurate (± 3º C) real-time temperature monitoring of the circulating irrigating fluid between 20°C and 60° C and includes a user adjustable alarm set point. The Wand is designed for use up to 15 minutes of cumulative active ablation and is currently cleared to be used with ArthroCare System 12000 (QUANTUM II). Alternately, the surgeon can control these functions with the optional foot pedal. A representative image of the Ambient HipVac 50 Wand is provided (Figure 1).

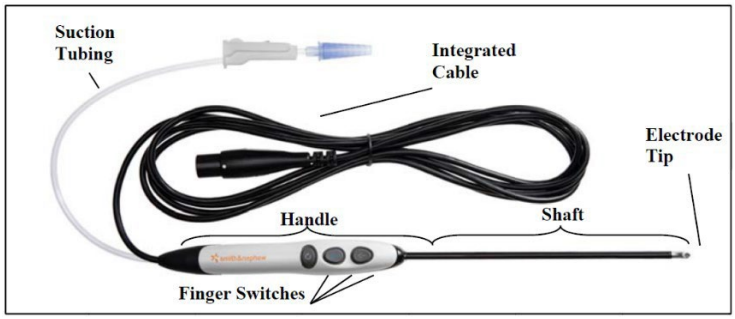

Figure 1: Ambient HipVac 50 Wand

7.4.2 WEREWOLF COBLATION Systems (RF20000, WEREWOLF, WEREWOLF+)

RF20000 COBLATION System (K162074)

The RF20000 COBLATION System consist 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 RF20000 Coblation System (K162074) utilizes bipolar technology specifically designed for the resection, and ablation of soft tissue and hemostasis of blood vessels in various arthroscopic and orthopedic procedures.

The RF20000 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): Hi (Ablation), Med (Ablation), Lo (Ablation), Vac (Vacuum), and COAG (Hemostasis).

WEREWOLF COBLATION SYSTEM (K192027)

The WEREWOLF COBLATION System consist 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 (cleared via 510(k) K192027) is an iteration of the RF20000 COBLATION system (K162074) and 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 COBLATION controller has the same hardware as the RF20000 (K162074); the software has been updated to increase functionality per the additional ENT indications. There have been no changes to the 18-pin wand functionality cleared in K162074.*

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 procedures (cleared via K192027).

WEREWOLF+ COBLATION SYSTEM (K210423)

The WEREWOLF COBLATION System consist 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 the RF20000 and WEREWOLF COBLATION system (cleared via 510(k)s K162074 and K192027, respectively). 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+ COBLATION controller has the same hardware as the RF20000 (K162074) and WEREWOLF Coblation System (K192027); the software has been updated to increase functionality per the additional indications: hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures. There have been no changes to the 18-pin wand functionality cleared in K162074.*

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

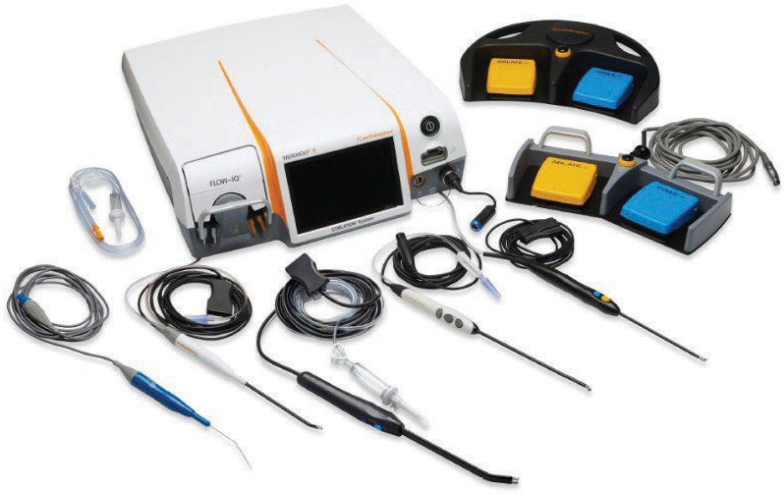

Figure 2: Werewolf Coblation Systems

7.5 INDICATIONS FOR USE

The Ambient HipVac 50 Wand with Integrated Finger Switches is indicated for the resection and ablation of soft tissue, and hemostasis of blood vessels less than 1mm (via coagulation) 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	▪ Acromioplasty ▪ Subacromial Decompression	▪ Frozen Shoulder Release ▪ Glenoidale Labrum
Wrist		▪ Triangular Fibrocartilage (TFCC)

7.6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The subject devices (Ambient HipVac 50 Wand used with the WEREWOLF COBLATION Systems) have the same technological characteristics (i.e., design, material, chemical composition, and energy source) as the predicate device (Ambient HipVac 50 Wand used with QUANTUM II) with the following exceptions highlighted in bold font (Table 7.1)

Table 7.1: Comparison of Technological Characteristics between the Predicate and Subject Systems

Parameter	**Primary Predicate System** HipVac 50 IFS (K161481) Predicate: Quantum II (K082666)	**Subject Device System 1** HipVac 50 IFS (K161481) RF20000 (K162074)	**Subject Device System 2** HipVac 50 IFS (K161481) Werewolf (K192027)	**Subject Device System 3** HipVac 50 IFS (K161481) Werewolf+ (K210423)
Controller Intended Uses				
Ablation / Resection	Yes	Same	Same	Same
Hemostasis / Coagulation	Yes	Same	Same	Same
Controller Specifications/Features				
Input Power	100-120/220-240V	Same	Same	Same
Fuse Rating	50/60 Hz	Same	Same	Same
Output Frequency	100 KHz	Same	Same	Same
Default Ablation Set Point / Output Voltage (Vrms)	Set Point 7 / 260	Same	Same	Same
Ablation Set Point Range / Output Voltage (Vrms)	Set Points 1-9 / 100-314	Same	Same	Same
Coagulation Set Point Range / Output Voltage (Vrms)	Set Points 1-2 / 65-100	Same	Same	Same
Output Control Mechanism	Wired or wireless foot pedal	Same	Same	Same
Weight	<5kg	**10 kg***	**10 kg***	**10 kg***
Controller crest factor	≤2	Same	Same	Same
Controller waveforms	Square wave	Same	Same	Same
Rated Wand voltage	320±10% Vrms	Same	Same	Same
Output Voltage (Vrms) at 350 ohm load	Set Point 0 / 0	Same	Same	Same
	Set Point 1 / 95	Same	Same	Same
	Set Point 2 / 120	Same	Same	Same
	Set Point 3 / 146	Same	Same	Same
	Set Point 4 / 171	Same	Same	Same

	Set Point 5 / 198	Same	Same	Same
	Set Point 6 / 224	Same	Same	Same
	Set Point 7 / 247	Same	Same	Same
	Set Point 8 / 273	Same	Same	Same
	Set Point 9 / 299	Same	Same	Same
	Set Point 10 / 320*	Same	Same	Same
	Coag 1 / 65	Same	Same	Same
	Coag 2 / 98	Same	Same	Same
Software Program	Software for Quantum II, V 2.03	**Graphic User Interface (GUI) V 1.4** **Main RF controller software V 2.5**	**Graphic User Interface (GUI) V 3.0** **Main RF controller software V 4.1**	**Graphic User Interface (GUI) V 5.0** **Main RF controller software V 6.1**
Graphical User Interface (GUI)	No	**Yes***	**Yes***	**Yes***
Integrated Fluid Outflow Regulator	No	**Yes***	**Yes***	**Yes***
Wand Specifications / Features				
Intended Use	Resection and ablation of soft tissues, and hemostasis of blood vessels less than 1mm (via coagulation) in the indicated arthroscopic and orthopedic procedures	Same	Same	Same
Shaft Length	176 mm			
Handle Length	141.75 mm	Same	Same	Same
Distal Bend Angle	50°	Same	Same	Same
Outer Diameter of Shaft	4.6 mm	Same	Same	Same
Sterilization	Radiation	Same	Same	Same
Electrical Safety/EMC	IEC 60601-2-2 compliant	Same	Same	Same
Suction and/or Irrigation	Yes	Same	Same	Same
Packaged Sterile	Yes	Same	Same	Same
Tyvek Packaging/Adhesive	Yes	Same	Same	Same
Operates in Saline Environment	Yes	Same	Same	Same
Bipolar / Monopolar	Bipolar	Same	Same	Same
Use Limiting Feature	Yes	Same	Same	Same
Software in Wand	No	Same	Same	Same

Single Use Disposable	Yes	Same	Same	Same
Recommended Active Ablation Time	15 min (cumulative ablation) at set point 7	Same	Same	Same
Wand Temperature Sensor (i.e., Ambient Feature)	T-Type thermocouple with range of 20-60º C ± 3 º C	Same	Same	Same
Activation	Foot Control or Integrated Finger Switches	Same	Same	Same

***Differences discussed below in section 7.5 Comparison of Subject and Predicate Devices**

7.6 COMPARISON OF SUBJECT AND PREDICATE DEVICES

7.6.1 WEREWOLF COBLATION Systems

Both the subject systems and the primary predicate system share the same intended use, indications of use, fundamental technology, and principle of operation. The technological differences include:

- Touch-controlled Graphical User Interface (GUI): The graphical user interface was an advancement of technology to improve ease of use and expand visual feedback options. No changes have been made to the interface screens cleared in K162074, K192027, K210423.

- Integrated Fluid Outflow Regulator: The integrated fluid outflow regulator was an advancement of technology which provides adjustable control of the rate of flow of conductive irrigating solution to or from the surgical site. No changes have been made to the Integrated Fluid Outflow Regulator cleared in K162074, K192027, K210423.

- 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 18 pin wands, (used by the HipVac 50 IFS). Please see K162074, K192027, and K210423 for all required software documentation.

- Weight: controller weight is a function of internal components, housing, and size.

7.6.2 AMBIENT HIPVAC 50 WAND

The technological characteristics for the Ambient HipVac 50 Wand subject device accessory has not changed compared to the predicate device accessory with the following exception highlighted in bold font (Table 7.2).

Table 7.2: Technological characteristics with the predicate device

PARAMETER	**PREDICATE DEVICE (K161481)** Ambient HipVac 50 IFS Wand	**SUBJECT DEVICE (K220563)** Ambient HipVac 50 IFS Wand
Controller	**QUANTUM 2***	**RF20000 COBLATION System*** **WEREWOLF COBLATION SYSTEM*** **WEREWOLF+ COBLATION SYSTEM***
Intended Use	Resection and ablation of soft tissues, and hemostasis of blood vessels less than 1mm (via coagulation) in the indicated arthroscopic and orthopedic procedures	Same
Wand Materials		
Electrode	Tungsten Alloy Metal Injection Molded (MIM)	Same
Spacer	Ceramic (Alumina)	Same
Adhesive	Epoxy (Loctite 3984)	Same
Shaft Suction line	PEEK	Same
Suction line	PVC	Same
Shaft	304 Stainless Steel	Same
Outer Shaft Insulation	Black PET Heat Shrink Tubing	Same
Wand Specifications		
Shaft Length	176 mm	Same
Handle Length	141.75 mm	Same
Distal Bend Angle	50°	Same
Outer Diameter of Shaft	4.6 mm	Same
Sterilization	Radiation	Same
Electrical Safety/EMC	IEC 60601-2-2 compliant	Same
Suction and/or Irrigation	Yes	Same
Packaged Sterile	Yes	Same
Tyvek Packaging/Adhesive	Yes	Same
Operates in Saline Environment	Yes	Same
Bipolar / Monopolar	Bipolar	Same
Use Limiting Feature	Yes	Same
Software in Wand	No	Same
Single Use Disposable	Yes	Same
Recommended Active Ablation Time	15 min (cumulative ablation) at set point 7	Same
Wand Temperature Sensor (i.e., Ambient Feature)	T-Type thermocouple with range of 20-60º C ± 3 º C	Same
Activation	Foot Control or Integrated Finger Switches	Same
18-pin	Yes	Same

*Controller: use of Ambient HipVac 50 with newer coblation system; WEREWOLF COBLATION SYSTEMS.

7.7 PERFORMANCE TESTING – NON-CLINICAL

For the non-clinical performance testing, the RF20000 COBLATION system was selected as the representative model for the WEREWOLF COBLATION Systems. Hardware and 18-pin software functionality (cleared via K161481) is identical across all controllers (RF20000, WEREWOLF, WEREWOLF+), therefore the non-clinical testing results are representative of the Ambient HipVac 50 wand with the WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423).

Functional tests included:

• Coagulation testing

• Ablation life (at 1X, 2X, 3X life)

• Ambient accuracy

• Finger switch functionality

• Shaft temperature

• Suction tube temperature

Because all required system level testing was previously conducted (cleared via K162074) and no changes have been made to impact device or system level requirements, the non-clinical testing conducted for this submission verified the RF20000 COBLATION System supports the wand specific requirements of the Ambient HipVac 50 wand; *results are representative of the Ambient HipVac 50 wand with the WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423) based on the rationale above.*

7.8 PERFORMANCE TESTING – PRE-CLINICAL

Pre-clinical bench testing (ex vivo testing) was conducted on the predicate (Ambient HipVac 50 Wand with QUANTUM II) and the representative subject (Ambient HipVac 50 Wand with RF20000 COBLATION System). Thermal effect width, ablation depth (amount of tissue removed) and thermal effect depth was measured in tissue models representing bovine myocardium (muscle), cartilage, meniscus, and tendon at the minimum, default, and maximum

ablation set points. Evidence obtained from preclinical bench testing (ex vivo) demonstrated that the Ambient HipVac 50 with RF20000 COBLATION System performs substantially equivalent to the predicate, Ambient HipVac 50 with QUANTUM 2. Since hardware and 18-pin functionality is identical across WEREWOLF COBLATION Systems (RF20000, WEREWOLF, WEREWOLF+), the pre-clinical testing results are representative of the Ambient HipVac 50 wand with the WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423) and support substantial equivalence to the predicate.

7.9 PERFORMANCE TESTING – ADDITIONAL

A comparison of the peak temperature of the electrode of the subject Ambient HipVac 50 wand in conjunction with the predicate QUANTUM II and representative subject RF20000 COBLATION system was conducted during ablation at the maximum set point. The data was measured using a Neoptix T1 fiber optic temperature probe (model T1S-02-W05-PT05) using a beef heart tissue model. Both controllers with the Ambient HipVac 50 wand were activated directly over the temperature probe for ten (10) seconds at maximum ablation setpoint (9) with auxiliary suction, as required by the device IFU. The maximum temperatures recorded using both controllers were similar and support evidence of substantial equivalence. Since hardware and 18-pin functionality is identical across WEREWOLF COBLATION Systems (RF20000, WEREWOLF, WEREWOLF+), the additional testing results are representative of the Ambient HipVac 50 wand with the WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423) and support substantial equivalence to the predicate.

7.10 PERFORMANCE TESTING – ANIMAL

No animal data are included in this submission.

7.11 PERFORMANCE TESTING – CLINICAL

No clinical data are included in this submission.

7.12 CONCLUSION

All testing demonstrates that the Ambient HipVac 50 Wand with the RF20000 COBLATION system performs as intended and has acceptable performance when used in accordance with its labeling. Hardware and 18-pin software functionality is identical across subject controllers (RF20000, WEREWOLF, WEREWOLF+), therefore testing results are representative of the Ambient HipVac 50 wand with the WEREWOLF COBLATION system (K192027) and WEREWOLF+ COBLATION System (K210423). The intended use, principle of operation, and fundamental scientific technology are equivalent to the primary predicate device (Ambient HipVac 50 Wand with QUANTUM II), the Ambient HipVac 50 Wand with WEREWOLF COBLATION systems is as safe and effective as the predicate device.