June 24, 2021

ArthroCare Corporation
Piedad Pena
Senior Regulatory Affairs Specialist
7000 West William Cannon Drive
Building One
Austin, Texas 78735

Re: K210423
Trade/Device Name: Werewolf+ Coblation System, Werewolf+ Controller, Werewolf Fastseal 6.0 Hemostasis Wand
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 19, 2021
Received: May 21, 2021

Dear Piedad Pena:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210423

Device Name
WEREWOLF™ + COBLATION™ SYSTEM
WEREWOLF™ + CONTROLLER
WEREWOLF™ FASTSEAL 6.0 Hemostasis Wand

Indications for Use *(Describe)*
WEREWOLF™ FASTSEAL 6.0 Hemostasis Wand:

The FASTSEAL 6.0 Wand, used with the WEREWOLF™ + COBLATION System, is indicated for hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures.

WEREWOLF™ + COBLATION™ SYSTEM - See Page 2

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ArthroCare®

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

	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 • Glenoid Labrum
Wrist		• Triangular Fibrocartilage (TFCC)
ENT	**Resection/Ablation/Coagulation**	
	• Tonsillectomy (including Palatine Tonsils) Tracheal • Adenoidectomy • Uvulopalatopharyngoplasty (UPPP) • Traditional Uvulopalatoplasty Control (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 • 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
Orthopedic	Hemostasis (via coagulation) of soft tissue and bone.	

Section 7 - 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 Austin, TX 78735
Contact Person	Shruthi Bhat Senior Regulatory Affairs Specialist **Phone:** 512-466-9296 **Email:** shruthi.bhat@smith-nephew.com

Date Prepared	**June 24, 2021**

7.2 DEVICE NAME(S)

Proprietary Name	WEREWOLF° + COBLATION° SYSTEM WEREWOLF° + Controller WEREWOLF° FASTSEAL 6.0 Hemostasis 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) Aquamantys Pump Generator System and Aquamantys 6.0 Bipolar Sealer – K052859

7.4 PRESUBMISSION Q192412, Arthroplasty Coagulation Wand (SMC153) approved on March 23, 2020

7.5 SUBJECT DEVICES

The subject devices include the WEREWOLF ° + (RF20000) COBLATION System, which includes the WEREWOLF° + Controller and the WEREWOLF° FASTSEAL 6.0 Hemostasis Wand.

The purpose of this traditional 510(k) submission is to obtain clearance for the subject devices; WEREWOLF° + COBLATION System, WEREWOLF° + Controller and WEREWOLF° FASTSEAL 6.0 Hemostasis Wand for additional indications of use i.e hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures.

7.5.1 WEREWOLF° + (RF20000) COBLATION° System

The subject WEREWOLF + COBLATION System (System) is an iteration of the WEREWOLF Controllers previously cleared via 510(k)s K143235, K162074, K192027 and K202006 which utilizes bipolar technology specifically designed for the resection, ablation, and coagulation of tissues and hemostasis of blood vessels in various arthroscopic, orthopedic (cleared via K143235 and K162074), and otorhinolaryngology (ENT) procedures (K192027 and K202006).

The subject WEREWOLF + COBLATION System consists of:

- A bipolar, radiofrequency (RF) generator (WEREWOLF + Controller, subject Controller) 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)/FASTSEAL 6.0 Hemostasis Wand (subject Wand)
- Reusable, non-sterile power cord.

The components are designed to be operated as a single unit and are for prescription use only.

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.

7.5.2 WEREWOLF° + Controller

The WEREWOLF + Controller is designed to deliver radiofrequency energy to the electrodes of the compatible 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 (setpoints), volume, etc. Ports for connecting the compatible Wands and the Foot Control are located on the front panel.

Accessories to the subject Controller include a Foot Control (wired/ wireless) (K053510, K143235 and K162074) and Smith and Nephew INTELLIO Tablet Application (K192876) (optional accessory which is not subject of this 510(k) submission) for the indications cleared via K162074 (resection, ablation, and coagulation of tissues and hemostasis of blood vessels in various arthroscopic and orthopedic indications). Otorhinolaryngology (ENT) indications (K192027 and K202006) and hemostasis (via) coagulation of soft tissue and bone in orthopedic procedures (proposed indications) are not supported on the INTELLIO Tablet Application.

7.5.3 WEREWOLF° FASTSEAL 6.0 Hemostasis Wand

The subject WEREWOLF° FASTSEAL 6.0 Hemostasis Wand is a bipolar, RF electrosurgical device used for specific indications in orthopedic surgeries. The Wand is indicated for hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures. It is intended for procedures using normal saline (0.9% NaCl) as the irrigation fluid for the Wand.

ArthroCare®

7.6 PROPOSED INTENDED USE/INDICATIONS FOR USE

7.6.1 WEREWOLF◇ + Controller

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

	Ablation/Debridement		Excision/Resection	
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	• Articular Cartilage • Bursectomy • Chondroplasty	• Scar Tissue • Soft Tissue • Synovectomy	• Articular Labrum • Capsule • Cysts	• Plica Removal • Scar Tissue • Soft Tissue
	• Fascia	• Tendon	• Ligament	• Synovial Membrane
	• Ligament		• Loose Bodies	• 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 • Glenoid Labrum	
Wrist			• Triangular Fibrocartilage (TFCC)	
ENT	**Resection/Ablation/Coagulation**			
	• Tonsillectomy (including Palatine Tonsils) Tracheal • Adenoidectomy • Uvulopalatopharyngoplasty (UPPP) • Traditional Uvulopalatoplasty Control (RAUP) • Nasal Airway Obstruction • Submucosal Palatal Shrinkage • Submucosal Tissue Shrinkage		• Nasopharyngeal/Laryngeal indications including Tracheal Procedures • Mastoidectomy • Myringotomy with Effective Hemorrhage • Papilloma • Keloids • Nasopharyngeal/Laryngeal Procedures • Polypectomy • Laryngeal Polypectomy	

	• Nasal Airway Obstruction by reduction of Hypertrophic Nasal Turbinates • Reduction of Turbinates for the treatment of Nasal Airway Obstruction	• Laryngeal Lesion Debulking • Cysts • Tumors • Neck Mass • Head, Neck, Oral, and Sinus Surgery • Tissue in the Uvula/Soft Palate for the treatment of Snoring
Orthopedic	**Hemostasis (via coagulation) of soft tissue and bone.**	

7.6.2 WEREWOLF◇ FASTSEAL 6.0 Hemostasis Wand

The FASTSEAL 6.0 Wand, used with the WEREWOLF◇+ COBLATION System, is indicated for hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures.

7.7 COMPARISON OF SUBJECT and PREDICATE DEVICES

WEREWOLF + Controller:

Both the subject and the predicate devices are designed for bipolar electrosurgical wand device operation and share the same intended use, principle of operation and fundamental scientific technology.

The technological differences include different input power/ voltage, operating frequency, controller waveform and output nominal voltage maximum.

FASTSEAL 6.0 Hemostasis Wand:

Both the subject and the predicate devices are bipolar electrosurgical wands and share the same intended use, principle of operation and fundamental scientific technology.

The technological differences include software in the subject Wand, different shaft materials, tip-sealing materials, number of electrode saline ports, saline port orientation, saline flow rate, activation options and using smaller subset of Coag setpoints for orthopedic use, similar power and output voltage, and reduced current limit.

Table 7.1 Comparison of the technological characteristics of subject and predicate devices

Parameter	**PREDICATE DEVICE**: Aquamantys® 6.0 Bipolar Sealer (K052859) with Aquamantys Pump Generator (K052859)	**SUBJECT DEVICE**: WEREWOLF FASTSEAL° 6.0 Wand with WEREWOLF° + Controller
Representation	 Aquamantys® 6.0 Bipolar Sealer  Aquamantys Pump Generator	 FASTSEAL 6.0 Hemostasis Wand  WEREWOLF° + Controller
Indications of Use for the controllers	The Aquamantys™ Pump Generator is an electrosurgical generator with a rotary peristaltic pump, which is for use only with Aquamantys single-use disposable bipolar devices for concurrent delivery of radiofrequency energy with saline for hemostatic sealing of soft tissue and bone at the operative site. It is intended for, but not limited to, endoscopic and open abdominal, orthopedic, spine and thoracic surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization). The Aquamantys System is for use only by qualified medical personnel properly trained in the use of electrosurgical equipment, technology and techniques.	The WEREWOLF°+ COBLATION System controller is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in arthroscopic, orthopedic and otorhinolaryngology (ENT) procedures.

	The Aquamantys™ Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with a qualified Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).	
Indications of Use for the wands	The Aquamantys™ Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with a qualified Pump Generator for delivery of RF energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopedic, spine, thoracic, and open abdominal surgery. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).	The FASTSEAL 6.0 Wand, used with the WEREWOLF° + COBLATION System, is indicated for hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures
Functionality	Coagulation	Same
Input Power / Voltage	90-110V ~ 4A 104-127V ~ 3.5A 207-253V ~ 1.85A	100-120V ~ 8A 220-240V ~ 4A
Input Frequency	50/60 Hz	Same
Fuse Rating	5 Amps @ 100 VAC 4 Amps @ 115 VAC 2 Amps @ 230 VAC	N/A (16 Amp fuse built into power supply and not replaceable; power supply has overcurrent protection)
Operating (Output) Frequency	370kHz	350kHz

Controller Waveform	Sinusoid	Square
Saline Inflow (Fluid Pump Mechanism)	Peristaltic	Same
Saline Outflow	None, requires auxiliary suction device	Same
Foot Pedal Capability	No	Yes (wired/wireless)
Coagulation Activation Indication	Audio and visual	Same
Setting Adjustment Interface	Control panel with physical buttons (analog)	Graphical User Interface (GUI) with digital buttons
Control Panel or GUI Options	Adjust Coag level, saline flow rate, priming	Same
Wand Distal Tip Configuration		
Monopolar / Bipolar	Bipolar	Same
Activation Limit	None	15 minutes
Bipolar Coagulation Level Range and Scale	20-100 (increments of 5) 100-200 (increments of 10)	110-200 (increments of 10)
Maximum Output Power	200W	195W
Wand Output Nominal Voltage Maximum	150Vrms	130Vrms
Handle Length	6 inches	Same
Shaft Materials (Wand Patient-Contacting Materials)	Molded ABS plastic	Polyolefin heat shrink insulation over dual stainless steel alloy shafts
Shaft Working Length	5 inches	Same

Distal Shaft Bend Angle (Relative to Rest of Shaft Length)	30°	Same
Rigid Construction	Yes	Same
Electrode Material (Wand Patient-Contacting Materials)	Stainless Steel Alloy	Same
Tip Sealing Material (Wand Patient-Contacting Materials)	Molded ABS plastic (components welded together)	HV-10 heat cure epoxy
Electrode Dimensions	Width – 0.14 inches Length – 0.22 inches Thickness - 0.14 inches	Width – Same Length – 0.26 inches Thickness - Same
Number of Saline Ports	2	4
Saline Flow Rate Range and Scale	3 total levels: Low, Medium, High(symbolized by 1-3 droplets on front panel)	5 total levels: 1-5(symbolized by 1-5 droplets on GUI)
Saline Delivery Method	Integrated saline delivery tubing, enters treatment site through ports on electrode	Same
Priming Options	Automatic (Timed)	Same
Saline Outflow	None, managed by external suction device	Same
Activation Options	Finger Switch	Finger Switch or Foot Pedal
Number of Wand Finger Switches	1 (Coag)	2 (Coag and Max Coag)
Software in the Wand	No	Yes
Biocompatible	Yes	Same
Sterilization	Ethylene Oxide	Same
Device Usage	Single use, disposable	Same
Prescription (Rx)/Over the Counter(OTC)	Prescription (Rx)	Same
Packaging Configuration	PETG tray and single Tyvek sterile barrier lid inside outer box	PETG tray with PETG insert and single Tyvek sterile barrier lid inside outer box

7.8 STERILIZATION

The FASTSEAL 6.0 Wand is sterilized utilizing 100% Ethylene Oxide (EtO or EO) gas via an existing validated EO Cycle. The evaluation and adoption are based on the principles outlined in AAMI TIR 28:2016. The sterilization method ensures a minimum sterility assurance level of 10^{-6}.

7.9 SHELF LIFE

Shelf life testing included environmental conditioning, transit conditioning, accelerated aging studies at T=1 year, packaging integrity testing - visual inspection of seal, gross leak (bubble emission), dye penetration, peel strength testing, and delamination

8.0 PACKAGING

The FASTSEAL 6.0 Wand is supplied sterile and is intended for single use only. The Wand is not to be cleaned or re-sterilized 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 + Controller is supplied non-sterile and is 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.

8.1 BIOCOMPATIBILITY

FASTSEAL 6.0 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.

8.2 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

The subject devices comply 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.

8.3 SOFTWARE

The overall software architecture for the WEREWOLF + Controller is the same as the previously cleared WEREWOLF Controller (K202006). The software was updated (Generator (version 6.1) and GUI (version 5.0)) to enable additional functionality of hemostasis (via coagulation) of soft tissue and bone in orthopedic procedures. The FASTSEAL 6.0 Wand software (version 4.8) is identical to the wand software cleared via K183346 and K192027. 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."

8.4 CYBERSECURITY

For the proposed expansion of indications, the WEREWOLF + ecosystem comprises the WEREWOLF + Controller and the FASTSEAL 6.0 Wand with wired/wireless Foot Control. The Cyber Failure Modes and Effects Analysis (CMEA) confirms that that there are no known unacceptable cybersecurity hazards associated with the subject devices and the WEREWOLF + platform.

8.5 PERFORMANCE TESTING

- **Non-clinical:**

  Non-clinical Performance testing assessed the design and performance of the subject devices to confirm they met the established design criteria and support the substantial equivalence with the predicate devices. It included verification testing of device performance and function which was successfully completed to ensure that the

subject devices met the established design specifications. It evaluated the mechanical, electrical, and functional performance of the device and verified that the differences between the subject and predicate devices did not alter the risk profile, performance characteristics, or specifications of the device.

- **Pre-clinical**

  Evidence obtained from preclinical bench testing (ex vivo) on multiple tissue models (bovine myocardium, porcine skeletal muscle, and porcine bone) demonstrated that the subject device, FASTSEAL 6.0 Wand performs substantially equivalent to the predicate device, Aquamantys 6.0 Wand. in relevant aspects associated with the Coagulation mode.

- **Additional bench testing**
  - Peak temperature testing at the distal electrodes included comparing the temperature of saline between the tip of the predicate and subject wands using a Neoptix fiber optic temperature probe and testing using a beef heart tissue model. The average peak tip temperature for the FASTSEAL 6.0 Wand was 97±4°C compared to 98±4°C for the Aquamantys 6.0 wand.

  - Peak temperature testing in a misuse scenario involved comparing peak saline temperatures of the FASTSEAL 6.0 Wand and Aquamantys 6.0 wand in worst case clinical misuse conditions where no auxiliary suction is used. Testing was conducted using a Neoptix fiber optic temperature probe and beef heart tissue model. The average peak saline temperature in the saline pooling test for the subject Wand was 81±3°C for the subject Wand and 87±2°C for the predicate wand; the average peak saline temperature in the saline runoff test was 79±1°C for the subject Wand and 83±2°C for the predicate wand.

  - Supplemental bench testing was conducted to assess and compare the potential differences between the FASTSEAL 6.0 Wand (subject device) and Aquamantys 6.0 wand (predicate device) across the range of flow rates in

regards to the thermal damage of the surrounding tissue. Myocardium tissue was evaluated at minimum, default, and maximum flow rate settings at the maximum energy setting for both the subject and predicate device. The results from this study demonstrated that saline flow rate has minimal effect on the total thermal effect width or maximum thermal depth for either the subject or predicate devices regardless of the flow setting. These results, as well as the results of the performance testing above, confirm substantial equivalence between the subject and predicate devices.

8.0 PERFORMANCE TESTING – ANIMAL

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

8.1 PERFORMANCE TESTING – CLINICAL

No clinical data are included in this submission.

8.2 CONCLUSION

All testing demonstrates that the subject devices perform as intended and have acceptable performance when used in accordance with its labeling.

ArthroCare Corporation evaluated the indications for use, technology, design and performance specification requirements of the subject devices and demonstrated that are as safe and effective as the predicate devices as intended for use.