



Food and Drug Administration
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August 22, 2016

ArthroCare Corporation
Ms. Shirley Hyink
Director, Regulatory Affairs
7000 W. William Cannon Drive
Austin, Texas 78735

Re: K162074

Trade/Device Name: Werewolf Coblation System (RF20000) with FLOW IQ Technology:
Werewolf System Controller (RF20000), and
FLOW 50 Wand

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: July 25, 2016

Received: July 27, 2016

Dear Ms. Hyink:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Christopher J. Ronk -S

FOR Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K162074

Device Name
Werewolf Coblation System (RF20000) with FLOW IQ Technology:
Werewolf System Controller (RF20000) and
FLOW 50 Wand

Indications for Use (Describe)
Please see attached.

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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The Werewolf Coblation System, comprised of the FLOW 50 Wand and the RF20000 Controller, is indicated for the resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures:

	Ablation/Debridement	Excision/Resection
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	<ul style="list-style-type: none"> ▪ Articular Cartilage ▪ Burssectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon 	<ul style="list-style-type: none"> ▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon
Hip		<ul style="list-style-type: none"> ▪ Acetabular Labrum ▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy ▪ Meniscectomy ▪ Villusctomy
Knee	<ul style="list-style-type: none"> ▪ ACL/PCL ▪ Notchplasty 	
Shoulder	<ul style="list-style-type: none"> ▪ Acromioplasty ▪ Subacromial Decompression 	<ul style="list-style-type: none"> ▪ Frozen Shoulder Release ▪ Glenoid Labrum ▪ Triangular Fibrocartilage (TFCC)
Wrist		

510(k) Summary

ArthroCare® Corporation

Werewolf Coblation System (RF20000) with FLOW IQ Technology

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.

General Information

Submitter Name: ArthroCare Corporation
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Contact Person: Shirley Hyink, BS
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Date Prepared: July 25, 2016

Device Name

Proprietary Name: Werewolf Coblation System (RF20000) with FLOW IQ Technology;
Werewolf System Controller (RF20000) and
FLOW 50 Wand
Common Name: Electrosurgical cutting and Coagulation Device and Accessories
Regulation Name: Electrosurgical cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Regulation Number: 21 CFR 878.4400

Predicate Devices

RF20000a Coblation System (K143235)

Description

Werewolf Coblation System(RF20000)

The RF20000 Coblation System is an electrosurgical system consisting of a bipolar radiofrequency Controller with Integrated Fluid Outflow Regulator; a sterile, disposable, single-use FLOW 50 Wand; Black Connector Quantum Wands, and a non-sterile, reusable wired Foot Control or wireless Foot Control.

This System 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 System offers five distinct Modes of operation: Hi (Ablation), Med (Ablation), Lo (Ablation), Vac (Vacuum), and COAG (Hemostasis). Each Ablation (Coblation) mode allows for precise ablation with minimal damage to surrounding healthy tissue. The COAG mode allows for consistent and precise hemostasis of blood vessels.

FLOW 50 Wand

The FLOW 50 Wand consists of a handle, shaft, integrated cable, and suction tubing. The integrated cable and suction tubing are attached at the proximal end of the handle and connect to the RF20000a Controller and the Fluid Outflow Regulator, respectively. The handle has finger switches that enable Ablation Mode switching (Lo, Med, Hi) as well as activation of the Wand (Vac, Coag, or Ablate). The Foot Control provides an alternate means of controlling these same functions. The Wand is provided sterile and is single-use only.

RF20000 Controller

The RF20000 Controller is designed to deliver radiofrequency energy to the electrodes of the FLOW 50 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 FLOW 50 Wand, Black Connector Quantum Compatible Wands and the Foot Control are located on the front panel. An optional wireless Foot Control can be installed.

The Controller incorporates a peristaltic integrated Fluid Outflow Regulator, which provides dynamic control of the rate of removal of conductive irrigating solution and/or fine, less dense, free-floating debris.

Intended Use/Indications for Use

The Werewolf Coblation System, comprised of the FLOW 50 Wand and the RF20000 Controller, is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in the following arthroscopic and orthopedic procedures:

	Ablation/Debridement	Excision/Resection
All Joints (Hip, Knee, Shoulder, Wrist, Ankle, Elbow)	<ul style="list-style-type: none"> ▪ Articular Cartilage ▪ Bursectomy ▪ Chondroplasty ▪ Fascia ▪ Ligament ▪ Scar Tissue ▪ Soft Tissue ▪ Synovectomy ▪ Tendon 	<ul style="list-style-type: none"> ▪ Articular Labrum ▪ Capsule ▪ Cysts ▪ Ligament ▪ Loose Bodies ▪ Plica Removal ▪ Scar Tissue ▪ Soft Tissue ▪ Synovial Membrane ▪ Tendon
Hip		<ul style="list-style-type: none"> ▪ Acetabular Labrum
Knee	<ul style="list-style-type: none"> ▪ ACL/PCL ▪ Notchplasty 	<ul style="list-style-type: none"> ▪ Capsular Release ▪ Cartilage Flaps ▪ Discoid Meniscus ▪ Lateral Release ▪ Meniscal Cystectomy

		<ul style="list-style-type: none"> ▪ Meniscectomy ▪ Villusectomy
Shoulder	<ul style="list-style-type: none"> ▪ Acromioplasty ▪ Subacromial Decompression 	<ul style="list-style-type: none"> ▪ Frozen Shoulder Release ▪ Glenoid Labrum
Wrist		<ul style="list-style-type: none"> ▪ Triangular Fibrocartilage (TFCC)

Summary of Technological Characteristics

The subject devices have the same technological characteristics (i.e., design, material, chemical composition, and energy source) as the predicate devices with the following exceptions (in bold font):

	<u>Predicate</u> Controller: RF20000a Wand: FLOW 50 (K143235)	<u>Subject</u> Controller: Werewolf Wand: FLOW 50
<i>Intended Uses</i>		
Ablation / Resection	Yes	Same
Hemostasis / Coagulation	Yes	Same
<i>Controller Specifications/Features</i>		
Input Power	100-240V 50/60Hz	Same
Fuse Rating	15 A	Same
Output Frequency (Fundamental)	100kHz	Same
Default Ablation Set Point / Output Voltage (Vrms)	Med• / 279	Same
Ablation Set Point Range / Output Voltage (Vrms)	Lo Minus – Hi Plus / 257-340	Same
Coagulation Set Point Range / Output Voltage (Vrms)	Coag – Coag Plus / 65-85	Same
Outflow Control Mechanism	Controller has an integrated low pressure rotational peristaltic pump Range: 0-600 rpm	Same
Software Program	Graphic User Interface V 0.2 RF controller software for	Graphic User Interface V 1.1

	Predicate Controller: RF20000a Wand: FLOW 50 (K143235)	Subject Controller: Werewolf Wand: FLOW 50
	RF20000a, V 1.0	RF controller software for RF20000, V 2.3
Weight	10 kg	Same
Controller crest factor (350 ohm load)	1.4	Same
Controller waveforms	Square	Same
Controller input power (W)	460 (290 ohms)	Same
Rated Wand voltage	340 Vrms	Same
Output Voltage (Vrms) at 350 ohm load	Lo - /126	Same
	Lo • / 150	Same
	Lo + / 175	Same
	Med - / 200	Same
	Med • / 224	Same
	Med + / 248	Same
	Hi - / 272	Same
	Hi • / 297	Same
	Hi + / 323	Same
	Coag / 53.2	Same
	Coag + / 102	Same
<i>Wand Materials</i>		
Electrode	Tungsten	Same
Shaft	304 Stainless Steel	Same
Outer Shaft Insulation	Black Pebax	Same
Spacer	Ceramic (Alumina)	Same
Adhesive	Epoxy (Loctite 3984)	Same
Handle Material	Iupilon S3001R	Same
Wand Suction Line	PVC	Same
<i>Wand Specifications/Features</i>		
Shaft length	5.31 ± 0.20 inches	Same
Distal Bend Angle	40 °	Same
Handle length	6.13 inches	Same
Number of Electrodes	1 active & 1 return	Same
Screen	Tungsten screen with welded	Same

	<u>Predicate</u> Controller: RF20000a Wand: FLOW 50 (K143235)	<u>Subject</u> Controller: Werewolf Wand: FLOW 50
(active electrode)	platinum iridium leads bonded to holes in spacer with epoxy	
Number of Internal Suction Ports	1	Same
Suction	Yes	Same
Shaft Rigid Construction	Yes	Same
Use Limiting Feature	Yes (microchip in the handle of the Wand that only allows the Wand to be used for 24 hours after activation)	Same
Temperature Measure	10 to 60 °C measured with a thermistor Ambient alarm: Audible & visual alarms active if measured irrigation fluid temp exceeds alarm set point. Measurement of tube in handle, preventing excessive tube temperature. Output pulsed or shut-off if temperatures exceeded.	Same
Finger Switch Activation	Yes	Same
Foot Switch Activation	Yes	Same
Software in Wand	FLOW 50 Wand Product Code V 3.2 Config File 48649	FLOW 50 Wand Product Code V 3.2 Config File 68909 (includes Wand Wear and LVI parameters)
Packaged Sterile	Yes	Same
Single Use Disposable	Yes	Same
Operates in Conductive Media Environment	Yes	Same
Bipolar/ Monopolar	Bipolar	Same
Sterilization	Radiation	Same
Recommended Active Ablation Time	Lo Mode: 10 minutes Med Mode: 4 minutes Hi Mode: 2 minutes	Same

<u>Reference Comparator</u> Controller: Quantum 2 (K082666) Wand: BCQC Wands (Various)	<u>Subject</u> Controller: Werewolf Wand: BCQC Wands
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	<u>Reference Comparator</u> Controller: Quantum 2 (K082666) Wand: BCQC Wands (Various)	<u>Subject</u> Controller: Werewolf Wand: BCQC Wands
<i>Intended Uses</i>		
Ablation / Resection	Yes	Same
Hemostasis / Coagulation	Yes	Same
<i>Controller Specifications/Features</i>		
Input Power	100-240V 50/60Hz	Same
Fuse Rating	8 A	Same
Output Frequency (Fundamental)	100kHz	Same
Default Ablation Set Point / Output Voltage (Vrms)	Set Point 7 / 260	Same
Ablation Set Point Range / Output Voltage (Vrms)	Set Points 1-9 / 100-314	Same
Coagulation Set Point Range / Output Voltage (Vrms)	Set Points 1-2 / 65-100	Same
Outflow Control Mechanism	Hospital Suction with Roller clamp to adjust flow control. Recommended suction: 200-400 mmHg	Same
Software Program	Software for Quantum 2, V 2.03	Graphic User Interface V 1.1 RF controller software for RF20000, V 2.3
Weight	<5 kg	10 kg
Controller crest factor (350 ohm load)	1.4	Same
Controller waveforms	Square	Same
Controller input power (W)	460 (290 ohms)	Same
Rated Wand voltage	320 Vrms	Same
Output Voltage (Vrms) at 350 ohm load	Set Point 0 / 0	Same
	Set Point 1 / 95	Same
	Set Point 2 / 120	Same
	Set Point 3 / 146	Same
	Set Point 4 / 171	Same
	Set Point 5 / 198	Same

	Reference Comparator Controller: Quantum 2 (K082666) Wand: BCQC Wands (Various)	Subject Controller: Werewolf Wand: BCQC Wands
	Set Point 6 / 224	Same
	Set Point 7 / 247	Same
	Set Point 8 / 273	Same
	Set Point 9 / 299	Same
	Set Point 10 / 320*	Same
	Coag 1 / 65	Same
	Coag 2 / 98	Same

The modifications made to the RF20000a Controller were:

- Rebranding – The system will be marketed under the name “Werewolf Coblation System with FLOW IQ Technology”.
- Software algorithm changes to detect electrode wear
- Software algorithm changes to add dynamic sensing of Low Voltage Impedance
- Backwards compatibility of the Controller with existing, previously cleared Quantum Coblation Wands
- Ability to customize user profile
- Compatibility with a wireless Foot Control

Non-Clinical Data

Bench testing was performed on both the proposed and predicate devices. The test results demonstrate that the proposed Werewolf Coblation System meets its design, performance, and safety specifications. Based on the test results, the proposed device performs as intended and mechanical properties are substantially equivalent to the predicate device when used in accordance with labeling.

Clinical Data

No clinical or animal data are included in this submission.

Substantial Equivalence

Non-clinical performance data such as design verification, software validation, demonstrated that the subject devices are substantially equivalent to the predicate devices and are safe and effective when used as intended.

Summary

The Werewolf Coblation System (RF20000) is substantially equivalent to the predicate devices. The differences between the Werewolf RF20000 Coblation System and the predicate devices do not raise any new concerns about the safety or effectiveness of the subject devices.