K062544 1/2

JAN - 3 2007

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

Allison Scott
11460 N. Meridian St., Suite 150
Carmel, IN 46032
Phone: (317) 569-9500 x106
Facsimile: (317) 569-9520

Contact Person: Allison Scott

Date: August 29, 2006

807.92(a)(2)

Trade Name:	AR1000 Ultrasonic Wound Therapy System
Common Name:	Ultrasonic Wound Therapy System
Classification Name(s):	Jet Lavage; Ultrasonic Surgical Instrument
Classification Number:	FQH; LFL; NRB

807.92(a)(3)

Predicate Device(s)

Misonix, Inc.	SonicOne Ultrasonic Wound Debridement System	K050776
Soring Gmbh	Sonoca 180 Ultrasound Dissection	K012753
Smith & Nephew	VersaJet Hydrosurgery System	K060782
Celleration	Celleration Mist Therapy System	K050129

807.92(a)(4)

Device Description

The AR1000 system uses ultrasound for selective tissue dissection and fragmentation and saline for irrigation of the wound bed over course of treatment.

807.92(a)(5)

Intended Use(s)

Selective dissection and fragmentation of tissue, wound debridement (acute and chro ic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the remo al of debris, exudates, fragments, and other matter.

K063547 2/3

510(k) Summary
AR1000
Arobella Medical, LLC

807.92(a)(6)

Technological Characteristics

COMPARISON TABLE	Arobella Medical AR1000 Ultrasonic Wound Therapy System	Misonix (www.misonix.com) SonicOne™ Ultrasonic Wound Debridement System	Soring Gmbh Medizintechnik (www.soering.com) Sonoca 180 Ultrasound Dissection	Celleration (www.celleration.com) Mist Therapy System	Smith & Nephew (wound.smith-nephew.com/us/Home.asp) VersaJet Hydrosurgery System
Indications For Use	Selective dissection & fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter. May promote healing of wound or tissue.	Ultrasonic debridement of wounds (including burns, diabetic ulcers, bedsores, and vaginal ulcers), soft tissues, and cleansing surgical sites	Selected dissection and fragmenting of tissue at the operation site during multi-medical discipline surgery (General Surgery, Neuro, Thoracic, Urology, and Gastro-Intestinal)	Promotes wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria	Wound debridement, soft tissue debridement, and cleansing of surgical site and burns
510(k) or PMA Submission / CFR Citation	To Be Submitted	K050776 (AUSS-6 Ultrasonic Surgical Aspirator System)	K012753	K032378 / K050129	K991383 / K011612 / K060782
Device Agent	High Intensity Ultrasound & Irrigation 35kHz / ?	High Intensity Ultrasound 22.5kHz / ?	High Intensity Ultrasound 25kHz / ?	High Intensity Ultrasound 40kHz / ?	Pressurized Fluid Stream & Evacuation
Agent Delivery	Irrigation & Contact Probe	Contact Probe	Contact Probe	Atomized Irrigant & Non-Contact Probe	Irrigation/Suction Nozzle
Agent Mechanism	Ultrasound for selective tissue dissection and fragmentation and irrigation of wound bed over course of treatment	General cavitation (thermal agitation and fragmentation) of wounds and tissues	General cavitation (thermal agitation and fragmentation) of wounds and tissues	Ultrasound wound cleansing and maintenance debridement	Pressurized stream and evacuation cuts, ablates, and removes tissue and foreign matter and surgically resects/removes material
Treatment Variable	Applicator size/positioning/contact-surface, frequency and duration of treatments; irrigation flow rate	Applicator size/positioning, frequency and duration of treatments	Applicator size/positioning, frequency and duration of treatments	Applicator positioning, frequency and duration of treatments; Mist flow rate	Applicator positioning, frequency and duration of treatments; flow and evacuation rate
Treatment Setting	Hospital, clinic, in-home, or intraoperative settings	Hospital, clinic, in-home, or intraoperative settings	Intraoperative setting	Hospital, clinic, or in-home settings	Hospital, clinic, or intraoperative settings

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

Arobella Medical, LLC
c/o Mr. Eliaz Babaev
President & Chief Executive Officer
5929 Baker Road, Suite 470
Minnetonka, Minnesota 55345

Re: K062544
Trade/Device Name: AR1000 Ultrasonic Wound Therapy System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LFL
Dated: December 12, 2006
Received: December 13, 2006

Dear Mr. Babaev:

This letter corrects our substantially equivalent letter of January 3, 2007.

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 (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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K062544

Indications for Use

510(k) Number (if known): K062544

Device Name: AR1000 Ultrasonic Wound Therapy System

Indications for Use:

Selective dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing irrigation of the site for the removal of debris, exudates, fragments, and other matter.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSP D.L

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062544