DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Arobella Medical LLC
Matthew Berscheid
Director of Quality and Regulatory Affairs
5929 Baker Road, Suite 470
Minnetonka, MN 55345

Re: K131096
Trade/Device Name: AR1000 Ultrasonic Wound Therapy System
Regulation Number: 21 CFR 878.4410
Regulatory Class: Class II
Product Code: NRB
Dated: April 03, 2014
Received: April 04, 2014

Dear Mr. Berscheid:

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" (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/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,

David Krause -S

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: DMC
510(k) Staff
Division
D.O.

Indications for Use

510(k) Number (if known): _K131096_

Device Name: AR1000 Series Ultrasonic Wound Therapy System

Indications For Use:

The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing via:

- Selective and non-selective dissection and fragmentation of soft and or hard tissue;
- Surgical, excisional or sharp-edge wound debridement (acute and chronic wounds, burns) for the removal of nonviable tissue including but not limited to diseased tissue, necrotic tissue, slough and eschar, fibrin, tissue exudates, bacteria and other matter.

Patient population is patients of any age with one or more wounds.
Patient population may also exhibit diabetes mellitus (DM).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

Division Sign-Off
Office of Device Evaluation

Indications for Use

510(k) Number (if known): _K131096_

Device Name: AR1000 Series Ultrasonic Wound Therapy System

Indications For Use:

The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing via:

- Site cleansing irrigation and lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue);
- Contact and or non-contact maintenance debridement for the removal of debris, exudates, fragments, bacteria, slough, fibrin, excised or fragmented tissue, and other matter.

IRRIGATION (LAVAGE) FLUID

- Irrigation fluid may be sterile de-ionized water, sterile saline solution, other approved wound therapy or debridement solution.

Patient population is patients of any age with one or more wounds.
Patient population may also exhibit diabetes mellitus (DM).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

Division Sign-Off
Office of Device Evaluation

Indications for Use

510(k) Number (if known): _K131096_

Device Name: AR1000 Series Ultrasonic Wound Therapy System

Indications For Use:

The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing by:

- Preparing the wound bed for graft or other subsequent procedures using contact and or non-contact techniques to achieve wound debridement.

Patient population is patients of any age with one or more wounds.
Patient population may also exhibit diabetes mellitus (DM).

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

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