

510(k) Summary
510(k) - AR1000 Series K131096
Arobella Medical, LLC

MAY 16 2014

510(k) Summary (K131096)

In accordance with the requirements of 21 CFR 807.92, Arobella Medical is submitting the following 510(k) summary for the AR1000 Ultrasonic Wound Therapy System and its variants. (Reference previous 510(k) K062544)

807.92(a)(1)

Submitter Information

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Date: May 16, 2014

807.92(a)(2)

Trade Names: AR1000/B Ultrasonic Wound Therapy System, AR1000/B Qoustic Wound Therapy System™ (QWTS), or Qoustic Choice Wound Therapy System
Common Name: Ultrasonic Wound Therapy System
Classification Name(s): Ultrasonic Surgical Instrument; Wound Cleaner, Ultrasound
Product Classification: Class II or in the alternate Unclassified
Product Code: LFL

807.92(a)(3)

Predicate Device(s)

Arobella Medical, LLC	AR1000 Ultrasonic Wound Therapy System	K062544
Misonix, Inc	SonicOne Ultrasonic Wound Debridement System	K112782
Celleration	Celleration Mist Therapy System	K122246
Soring GmbH	SONOCA 180 / 185 Wound Care System	K072904

807.92(a)(4)

Device Description

The AR1000 Ultrasonic Wound Therapy System and its variants use ultrasonic energy from a generator delivered by a conductive cable to a hand held converter through the converter's distal end probe and liquid coupling medium: to perform wound therapy; to perform ultrasonic surgical, excisional, and or sharp-edge selective dissection procedures; with the intended end result to promote healing.

The AR1000 Ultrasonic Wound Therapy System generator utilizes commonly available wall outlet power (85 -260VAC, 50/60Hz) to produce the ultrasonic signal. A conductive cable connects the generator to the hand held converter. The hand held converter converts the signal into ultrasonic mechanical displacement in the distal end probe or Qurette. The ultrasonic mechanical displacement energy is applied to the treatment site by the distal end probe or Qurette through direct contact or non-contact techniques. The ultrasonic mechanical displacement energy is also transmitted as ultrasonic energy to the treatment site via the liquid coupling medium.

The AR1000 Ultrasonic Wound Therapy System distal end probe or Qurette is used with contact or non-contact modes to achieve intended wound therapy modalities to promote wound healing. This is achieved through the use of the low-frequency, controlled-intensity, ultrasonic energy to perform ultrasonic dissection and fragmentation of tissues, debridement of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue), and surgical, excisional or sharp-edge incisions.

The AR1000 Ultrasonic Wound Therapy System distal end probe or Qurette is used with contact or non-contact modes to achieve wound therapy and promotes wound healing through the ultrasonic dissection and fragmentation of tissues, debridement of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) through the use of the low-frequency, controlled-intensity, non-thermal ultrasonic energy.

The AR1000 Ultrasonic Wound Therapy System ultrasonic energy, via the liquid coupling medium to the treatment site, promotes wound healing through the lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing irrigation of the site for the removal of debris, exudates, fragments, bacteria, and other matter.

The AR1000 Ultrasonic Wound Therapy System uses continuous ultrasonic energy to propel the liquid medium (e.g. sterile saline, or other appropriate US FDA cleared medium) into a solution stream and couples the delivery of ultrasonic energy to the treatment site. This is accomplished by the ultrasonic energy application to the

510(k) Summary
510(k) - AR1000 Series K131096
Arobella Medical, LLC

treatment site where the ultrasonic energy is transmitted via the converter probe (Qurette) and also coupled via the liquid medium to the treatment site.

The converter has a transducer horn that is made from titanium alloy (TI-6AL-4V). The converter probe Qurette tips are made from titanium alloy (TI-6AL-4V),

No latex is used in this device, including any potential patient-contact areas, and testing has revealed no negative reactions to the materials used in this device.

Specifications:

Generator Power Source	85 -260V~ (VAC), 2.5A, 50/60Hz
Converter Power Output	<140 watts
Amplitude (adjustable)	0um ~ 75um (0% to 100% power level)
Frequency	35kHz (\pm 3kHz)
Weight	Generator: ~12.5 lbs Handheld Converter: ~1.0 lbs
Approximate Dimensions inches Height diameter	System 15 inches Deep x 12 inches Wide x 6 Handheld Converter: 9 inches x 1.3 inches
Storage Temperature 90%	-20 to +50° C at a maximum relative humidity of (non-condensing)
Operating Temperature	0 to +40° C at a maximum relative humidity of 90% (non-condensing)

510(k) Summary
510(k) - AR1000 Series K131096
Arobella Medical, LLC

807.92(a)(5)

Intended Use(s)

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).

The AR1000 Series and its variants is intended for Prescription 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).

The AR1000 Series and its variants is intended for Prescription use.

510(k) Summary
510(k) - AR1000 Series K131096
Arobella Medical, LLC

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).

The AR1000 Series and its variants is intended for Prescription use.

510(k) Summary
510(k) - AR1000 Series K131096
Arobella Medical, LLC

807.92(a)(6)

Technological Characteristics

There have been no changes to the AR1000 Ultrasonic Wound Therapy System cleared under 510(k) K062544 as a result of the proposed labeling changes.
The following Tables illustrate similarities and differences between the submitted AR1000 Ultrasonic Wound Therapy System and the predicate devices.

510(k) Summary
 510(k) - AR1000 Series K131096
 Arobella Medical, LLC

Table 1: Comparison of Technical Characteristics Table – Specified Indications For Use with Identified Predicates

Device	Arobella AR1000 (Proposed K131096)	Arobella AR1000	Misonix SonicOne	Celleration Mist
510(k) Indications for Use per indicated US FDA 510(k)	<p>The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing via:</p> <ul style="list-style-type: none"> • 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. 	<p>K062544</p> <p>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.</p>	<p>K112782</p> <p>The Misonix SonicOne is indicated for use in the debridement of wounds, such as, but not limited to: burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.</p>	<p>K122246</p> <p>The MIST Therapy system produces a low energy ultrasound generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.</p>

510(k) Summary
 510(k) - AR1000 Series K131096
 Arobella Medical, LLC

Table 2: Comparison of Technical Characteristics Table – Specified Indications For Use with Identified Predicates

Device	Arobella AR1000 (Proposed K131096)	Arobella AR1000	Misonix SonicOne	Celeration Mist	Soring Sonoca
510(k) Indications for Use per indicated US FDA 510(k)	The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing via: <ul style="list-style-type: none"> • Site cleansing irrigation and lavage of wound tissue (acute and chronic wounds, burns, diseased or necrotic tissue); • Contact and non-contact maintenance debridement for the removal of debris, exudates, fragments, bacteria, slough, fibrin, excised or fragmented tissue, and other matter. IRRIGATION (LAVAGE) FLUID <ul style="list-style-type: none"> • Irrigation fluid may be sterile de-ionized water, sterile saline solution, other approved wound therapy or debridement solution. 	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.	K112782 The Misonix SonicOne is indicated for use in the debridement of wounds, such as, but not limited to: burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.	K122246 The MIST Therapy system produces a low energy ultrasound generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.	K072904 The SONOCA 180 / 185 Wound Care system is an instrument intended for selected ultrasound dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing irrigation of the site for removal of debris, exudates, fragments, and other matter.

510(k) Summary
 510(k) - AR1000 Series K131096
 Arobella Medical, LLC

Table 3: Comparison of Technical Characteristics Table – Specified Indications For Use with Identified Predicates

Device	Arobella AR1000 (Proposed K131096)	Arobella AR1000	Misonix SonicOne	Celleration Mist	Soring Sonoca
510(k) Indications for Use per indicated US FDA 510(k)	<p>The AR1000 Series and its variants produce and deliver low frequency ultrasound used to promote wound healing by:</p> <ul style="list-style-type: none"> • Preparing the wound bed for graft or other subsequent procedures using contact and or non-contact techniques to achieve wound debridement. 	<p>K062544</p> <p>Selective dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue), and cleansing of irrigation of the site for the removal of debris, exudates, fragments, and other matter.</p>	<p>K112782</p> <p>The Misonix SonicOne is indicated for use in the debridement of wounds, such as, but not limited to: burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgment would require the use of an ultrasonic aspirator with sharp debridement.</p>	<p>K122246</p> <p>The MIST Therapy system produces a low energy ultrasound generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria.</p>	<p>K072904</p> <p>The SONOCA 180 / 185 Wound Care system is an instrument intended for selected ultrasound dissection and fragmentation of tissue, wound debridement (acute and chronic wounds, burns, diseased or necrotic tissue) and cleansing of irrigation of the site for removal of debris, exudates, fragments, and other matter.</p>

510(k) Summary
 510(k) - AR1000 Series K131096
 Arobella Medical, LLC

Table 4: Comparison of Technical Characteristics Table continued

Device	Arobella AR1000	Arobella AR1000	Misonix SonicOne	Celleration Mist	Soring Sonoca
510(k) number	This submission K131096	K062544	K112782	K122246	K072904
Device Agent	High Intensity Ultrasound and irrigation 35KHz	High Intensity Ultrasound and irrigation 35KHz	High Intensity Ultrasound 22.5KHz	High Intensity Ultrasound 40KHz	High Intensity Ultrasound 40KHz
Agent Delivery	Irrigation, atomized irrigation, contact, and non-contact probe	Irrigation, atomized irrigation, contact, and non-contact probe	Contact probe	Atomized irrigant and Non-contact probe	Contact probe
Agent Mechanism	Ultrasound for selective tissue dissection, fragmentation, and irrigation of wound bed over course of treatment	Ultrasound for selective tissue dissection, fragmentation, and irrigation of wound bed over course of treatment	General cavitation (thermal agitation and fragmentation) of wounds and tissue	Ultrasound wound cleansing and maintenance debridement	General cavitation (thermal agitation and fragmentation) of wounds and tissue
Treatment Variable	Applicator size, positioning, contact surface, frequency and duration of treatments, irrigation flow rate	Applicator size, positioning, contact surface, frequency and duration of treatments, irrigation flow rate	Applicator size, positioning, frequency and duration of treatments	Applicator positioning, frequency and duration of treatments, Mist flow rate	Applicator size, positioning, frequency and duration of treatments
Treatment Setting	Hospital, clinic, in-home, or intra-operative settings	Hospital, clinic, in-home, or intra-operative settings	Hospital, clinic, in-home, or intra-operative settings	Hospital, clinic, or in-home settings	Intra-operative settings

807.92(b)

Safety and Effectiveness

There have been no changes to the AR1000 Ultrasonic Wound Therapy System cleared under 510(k) K062544 as a result of the proposed labeling changes.

This 510(k) submission supports an expansion of the device's Indications For Use, with respect to K062544, to incorporate expanded patient results and laboratory findings.

The expansion of the device's Indications For Use, with respect to K062544, do not raise any new issues of safety or effectiveness.

For safety and effectiveness purposes the AR1000 Ultrasound Wound Therapy System and its variants is substantially equivalent to the previously cleared AR1000 Ultrasound Wound Therapy System (K062544), the Misonix SonicOne (K112782) system, Celleration MIST (K122246) system, the Soring Sonoca (K072904) systems, and the Ethicon (K002906) system.

1.0 Efficacy

This device, like the predicates, is directed for single (1) treatment, and total recommended treatments shall be no more than three (3) times per week or as directed on the order of the physician. A typical treatment regimen is approximately two (2) weeks or more, depending on the size and nature and or condition of the treated area as well as other subject dependent factors, but may be prescribed for more or less frequent use and or for shorter or longer treatment regimen durations on the order of a physician.

This device also compares with the predicates, as follows:

1.1. Controlled ultrasonic delivery with 0.9% sterile saline solution, or other approved medium, to lavage the wound tissue (e.g. acute and chronic wounds, burns, diseased or necrotic tissue), like the Arobella AR1000 (K062544) system and the Celleration (K122246) predicate ultrasonic wound system.

1.2. Maintenance debridement of the treatment site for the removal of loose fragments, debris, exudate, bacteria, and other matter, like Arobella AR1000 (K062544) system, the Misonix SonicOne (K112782) system, the Celleration (K122246) system, and the Soring Sonoca (K072904) predicate ultrasonic wound system.

1.3. Ultrasonic selective dissection and debridement of tissue through the use of the probe (aka Qurette), including parallel to the wound bed surface for shallow separation of tissue layers, like the predicate Arobella AR1000 (K062544) system and the Misonix SonicOne (K112782) system.

2.0 Safety

The AR1000 Ultrasonic Wound Therapy System and its variants consists of an ultrasonic power supply (hereto after referred to as a generator), an ultrasonic converter hand piece (or just converter), and distal end probe tip (Qurette), a liquid supply reservoir and delivery tubing. Substantial equivalence has been previously established between the AR1000 Ultrasonic Wound Therapy System (K062544) and the Celleration Mist, and the Misonix SonicOne predicate ultrasonic wound cleanser devices as outlined under K062544.

2.1 Electrical Safety & Electromagnetic Compatibility

Similar to the relevant predicates, this device complies with the following standards:

- IEC 60601-1 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical electrical equipment, Part 1-2: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-4 Medical electrical equipment, Part 1-4: Programmable electrical medical systems
- FCC Part 18 - EMC Requirements

2.2 Ultrasonic Safety

Similar to the relevant predicates, this device complies with the following standards:

- 21 CFR 1050.10 – Ultrasonic therapy products
- IEC 61847 Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics

510(k) Summary
510(k) - AR1000 Series K131096
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2.3 Biocompatibility

Similar to the relevant predicates, this device was tested for and complies with the standard ISO 10993-1:2003 - Biological evaluation of medical devices, Part 1: Evaluation and testing and its relevant annexes (based on nature and duration of patient contact). All testing was conducted in compliance to 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies.

The AR1000 system is routinely used with 0.9% sterile saline solution, which is widely available for purchase from medical suppliers in bottle or bag form and is to be supplied by the user, as well as the tubing and the valve (for saline flow control). In the alternate, the AR1000 can also be used with other appropriate sterile mediums and US FDA-approved irrigation liquids. This is substantially equivalent to all of the predicate devices and irrigation solutions.

2.4 Transportation/Storage

Packaging systems for the non-sterile device and for the non-sterile accessories of the device (e.g. the converter, tips, shroud, et al) keep the product without deterioration and without a specific level of sterility stipulated, as do the predicate devices. Those accessories used specifically for treatment (e.g. converter, tip, shroud, etc) are to be sterilized prior to use to minimize the risk of microbial contamination, as established with the AR1000 K062544 device clearance.

As the device and the accessories are durable goods with little or no notable deterioration, the shelf life is the product lifecycle, barring storage or transportation damage, and/or use under extremes of environmental conditions (e.g. temperature, humidity, moisture, etc).

2.5 Reprocessing

The AR1000 system, as well as the AR1000 ultrasonic converter hand piece, is the wound debridement device cleared under K062544 for which reprocessing instructions have been previously validated and cleared.

The variant AR1000 ultrasonic converter hand piece allows for steam sterilization (autoclave) in addition to the previously cleared and validated reprocessing methodology. This variant may therefore be reprocessed by steam sterilization (autoclave), as well as the previously cleared and validated reprocessing methodology.



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" (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,

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

510(k) _K131096_

Page 1 of 3

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
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

Division Sign-Off
Office of Device Evaluation

510(k) _K131096_

Page 2 of 3

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

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510(k)_K131096_

Page 3 of 3