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

August 25, 2017

BRH Medical Ltd.
% Susan D. Goldstein-Falk
Vice President – FDA Compliance
mdi Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: K160378
Trade/Device Name: BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI, IPF, LIH, IMG
Dated: July 27, 2017
Received: July 28, 2017

Dear Ms. Goldstein-Falk:

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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K160378

Device Name
BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)

Indications for Use *(Describe)*

Therapeutic Ultrasound:
1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation:
1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

TARGET POPULATION
Adult patients

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.

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K160378 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

General Information:

Applicant:	BRH Medical Ltd. The Jerusalem Technological Gardens Building A, 1st Floor Jerusalem, 96951, Israel Tel: + 02-6483519
Contact Persons:	
CEO	Motti Oderberg Tel: ++ 972 (0)54-6772277 E-mail: Motti@026430010.co.il
CTO	ILAN Feferberg Tel: ++972 (0)54-6678330 E-mail: imft@zahav.net.il
Date Prepared:	August 24, 2017
Device Trade Name:	BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)
Common or Usual Name:	Ultrasonic diathermy for Use in Applying Therapeutic Deep Heat
Classification Name:	Ultrasonic Diathermy (21 CFR 890.5300)
Regulatory Class:	Class II
Product Code:	IMI
Common or Usual Name:	Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat
Classification Name:	Ultrasound and muscle stimulator (21 CFR 890.5860)
Regulatory Class:	Class II
Product Code:	IMG

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Common or Usual Name:	Stimulator, Muscle, Powered
Classification Name:	Powered muscle stimulator (21 CFR 890.5850)
Regulatory Class:	Class II
Product Code:	IPF

Common or Usual Name:	Interferential Current Therapy
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief (21 CFR 882.5890)
Regulatory Class:	Class II
Product Code:	LIH

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Primary Predicate Device: Trade Name Sonicator® Plus 930
(Combination ultrasound and muscle stimulator) Mettler Electronics Corp.
K013192

Secondary Predicate Device: Trade Name The DU857 Dual Frequency Ultrasound Therapy and Muscle Stimulator System
Alfa Tech Medical Systems Ltd.
K052340

Device Description:

The BRH-A2 CUSEFS is comprised of the following main components:

- A system console including software and control electrodes;
- A control and display panel
- Specially designed cart
- User-friendly touch screen
- The BRH-A2 CUSEFS is powered by standard one phase 120 or 230 V power supply.

The BRH-A2 CUSEFS is a two-channel combination unit for therapeutic ultrasound and 4-Pole Interferential Current therapy folded into a specially designed cart. The microprocessor controlled BRH-A2 CUSEFS provides 4-Pole Interferential Current therapy alternating current with enhanced reliability and user friendly interface. The BRH-A2 CUSEFS offer 1 and 3 MHz ultrasound treatment modes.

There is a user-friendly touch screen interface. The screen provides operator information about operation mode and signal intersities. Large control knobs on the touch screen make adjusting power for ultrasound and muscle stimulation.

The BRH-A2 CUSEFS can provide 4-Pole Interferential Current therapy only and ultrasound treatment only.

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Indications for Use:

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) is intended for ultrasound and neuromuscular stimulation

Therapeutic Ultrasound:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase of blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain
2. Temporary relaxation of muscle spasm
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles
4. Increase of blood flow in the treatment area.
5. Prevention or retardation of disuse atrophy in post-injury type conditions
6. Muscle re-education
7. Maintaining or increasing range of motion

TARGET POPULATION

Adult patients

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Substantial Equivalence Comparison of Subject Device to Predicate Devices

Parameter	**BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) K160378**	**Primary Predicate Sonicator Plus 930 K013192**	**Secondary Predicate DU857 K052340**
Trade Name	BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS)	Sonicator Plus 930	DU857
510(k) number	K160378	K013192	K052340
Classification Name	Ultrasonic Diathermy for Use in Applying Therapeutic Deep Heat, Stimulator, Ultrasound And Muscle, For Use In Applying Therapeutic Deep Heat, Stimulator, Muscle, Powered and Interferential Current Therapy	Ultrasonic Diathermy, Powered Muscle Stimulator, Transcutaneous Electrical Nerve Stimulator for Pain relief and Interferential Current Therapy.	Ultrasound and Muscle Stimulator
Model Number	BRH-A2	ME930	DU857
Product Code	IMI, IMG, IPF, LIH	IMI, GZJ, IPF, LIH	IMI, IMG, IPF, LIH
Manufacturer	BRH Medical Ltd.	Mettler Electronics	Alfa Tech Medical Systems Ltd
Indications for use	Therapeutic Ultrasound: 1. Pain relief 2. Reduction of muscle spasm 3. Localized increase of blood flow 4. Increase range of motion of contracted joints using heat and stretch techniques. Neuromuscular Stimulation 1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain 2. Temporary relaxation of muscle spasm 3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles 4. Increase of blood flow in	Therapeutic Ultrasound: 1. Pain relief 2. Reduction of muscle spasm 3. Localized increase of blood flow 4. Increase range of motion of contracted joints using heat and stretch techniques. Neuromuscular Stimulation 1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain (Interferential and Pre-modulated waveforms) 2. Temporary	Therapeutic Ultrasound: 1. Pain relief 2. Reduction of muscle spasm 3. Localized increase of blood flow 4. Increase range of motion of contracted joints using heat and stretch techniques. Neuromuscular Stimulation 1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute surgical pain

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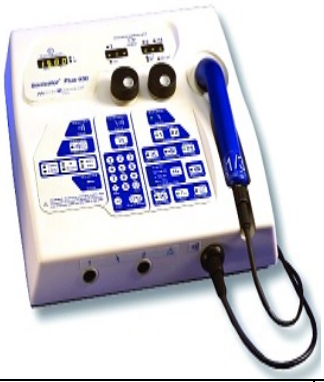
	the treatment area. 5. Prevention or retardation of disuse atrophy in post-injury type conditions 6. Muscle re-education 7. Maintaining or increasing range of motion TARGET POPULATION Adult patients	relaxation of muscle spasm(all waveforms) 3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles(all waveforms) 4. Increase of blood flow in the treatment area(all waveforms) 5. Prevention or retardation of disuse atrophy in post-injury type conditions(all waveforms) 6. Muscle re-education(all waveforms) 7. Maintaining or increasing range of motion(all waveforms)	2. Temporary relaxation of muscle spasm 3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles 4. Increase of blood flow in the treatment area. 5. Prevention or retardation of disuse atrophy in post-injury type conditions 6. Muscle re-education 7. Maintaining or increasing range of motion
Design and Appearance			
Size (HxWxD)	22 x 16.5 x 12 in	6 x 12 x 12 in	67 X 26 X 35 in
Weight	22 pounds	10 pounds	165 pounds
Design	The concept is to combine two kinds of therapeutic methods in a	The concept is to combine two kinds of therapeutic	The concept is to combine two kinds of

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	compact unit.	methods in one device	therapeutic methods in one device
Overall design difference	Separate touch screen controls both ultrasound & neuromuscular stimulation	A membrane panel and a touch screen to set up treatments	A membrane panel and a touch screen to set up treatments
Materials	Metal enclosure	Metal enclosure	Metal enclosure
Housing materials	Folded into a box shape and seams welded & ground flush and a stylized ABS cover screwed onto metal box	Folded into a box shape and seams welded & ground flush and a stylized ABS cover screwed onto metal box	Aluminum chassis
Performance	Use friendly interface, easy to operate	Use friendly interface, easy to operate	Use friendly interface, easy to operate
Target population	Adult patients	Patients who need Therapeutic Ultrasound and or Electrotherapy treatments	Patients who need physiotherapy treatment
Environment(s) of use	Physical therapy clinics; hospitals	Physical therapy clinics; hospitals	Physical therapy clinics; hospitals
BASIC UNIT CHARACTERISTICS			
Power source	AC Line	AC Line	AC Line
Power input	90-264 VAC, 50-60 Hz	90-240VAC, 50-60Hz	90-132VAC, 50-60Hz,4A; 207-264VAC, 50Hz, 2A
Method Line current isolation	Yes Isolation transformer	Yes	Yes
Operating temperature	+50°F to +104°F	+50°F to +104°F	+50°F to +86°F
Humidity	Operating, 30% to 75% RH (not condensed) Storage, 20% to 80% RH (not condensed)	Operating, 30% to 75% Relative Humidity (RH) at 104°F Storage, 5% to 95% RH (not condensed)	Operating, 30% to 75% Relative Humidity at 86°F Non operating, 20 to 80% Relative Humidity, noncondensing
Storage temperature	40°F to 167°F	40°F to 167°F	32°F to 113°F 0°C to 45°C
Indicator display On/off status	Yes	Yes	Yes
Treatment timer	Treatment time counts down to zero when time is set	Treatment time counts down to zero when time is set	Treatment time counts down to zero when a time is set, or up to 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the "Hold" period

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Timer Accuracy	± 0.5 seconds for all times range	±0.5 minutes for times less than 5 minutes tl 0% for times from 5 to 10 minutes ±1.0 minute for times greater than 10 minutes	± 5 seconds for all times range
Number of channels	2	2	2
Software control	Yes	Yes	Yes
Automatic overload trip	Yes	Yes	Yes
Insulation	BF	BF	BF
Patient override control	Yes	Yes	Yes
Maximum Treatment Time	30 minutes - ultrasound therapy 30 minutes – neuromuscular stimulation	30 minutes - ultrasound therapy 60 minutes – neuromuscular stimulation	30 minutes – ultrasound therapy 30 minutes – neuro muscular stimulation
Treatment Timer	Treatment time counts down to zero when time is set, or up to 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the 'Hold' period.	Treatment time counts down to zero when time is set, or up to 60 or 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the 'Hold' period	Treatment time counts down to zero when time is set, or up to 60 or 30 minutes when no time is set. The digital timer indicates the remaining or elapsed treatment time during the 'Hold' period
Power Indicator	Yes	Yes	Yes
Operational Indicator	Yes	Yes	Yes
THERAPEUTIC ULTRASOUND			
Transducer	4 cm^2 transducer	5 cm^2 transducer	5 cm^2 transducer
Frequencies	1.0 MHz ± 5% to 3.0 MHz ± 5%	1.0 MHz ± 5% to 3.0 MHz ± 5%	1.0 MHz ± 5% to 3.0 MHz ± 5%
Modes	Continuous Not applicable Not applicable	Continuous Pulsed - 20% duty cycle Pulsed - 50% duty cycle	Continuous
Pulse repetition rate	Not applicable	100 Hz ± 20%	Unknown
Pulse duration	Not applicable	2 msec±20%, 20% duty cycle	Unknown
Temporal peak / average intensity ratio	Not applicable	5:1±20%, 20% duty cycle	Unknown
Maximum	8 W with at 4 cm^2 applicator	11W with a5 cm^2	7W with a5 cm^2

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output power	(Ma-11cb)	applicator, (ME 1513)	applicator,
Maximum intensity	2.0 W/cm^2	2.2 W/cm^2	1.5 W/cm^2
Indication Accuracy	±20% (for any level above 10% of maximum)	±20% (for any level above 10% of maximum)	±20% (for any level above 10% of maximum)
Fixed treatment head placement	Not Applicable	Not Applicable	Unknown
Treatment head weight	0.250 KG	Unknown	Unknown
Leakage current	0.003 µA	Unknown	Unknown
Crystal material	PZT807	Unknown	Unknown
Technology of ultrasound generation (e.g., piezoelectric, magnetostrictive)	Piezoelectric	Piezoelectric	Piezoelectric
Beam maximum intensity and accuracy (W/cm2)	2 W/cm2±5%	Unknown	Unknown
THERAPEUTIC ULTRASONIC APPLICATOR SPECIFICATIONS			
Applicator Part Number	Ma-11cb	ME7513	
Treatment head dimensions	D4.5x 15.5cm	D5.5x 17cm	Unknown
Transducer contact face Biological evaluation	303 stainless steel	303 stainless steel	The output transducer utilizes a barium titanate disc with a specially coated face
Contact Monitor	Light on transducer	Light on transducer	Light on transducer
Frequency	1.0 MHz ± 5% to 3.0 MHz ± 5%	1.0 MHz ± 5% to 3.0 MHz ± 5%	1.0 MHz ± 5% to 3.0 MHz ± 5%
Beam type	Collimated	Collimated or divergent	Collimated
Effective Radiating Area ERA	4 cm^2±10%	5 cm^2±10%	5 cm^2±10%
Maximum Beam Non Uniformity Ratio BNR	<5	6:1	6:1
Peak temperature	N/A	N/A	Unknown

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rise vs. time and tissue depth to Maximum treatment time (for fixed treatment head placement) (°C)	N/A	N/A	
Maximum patient contact surface temperature of treatment head under simulated	Continually operated for maximum treatment time - 32.1°C Under simulated use conditions	Unknown	Unknown
Ultrasound Timer range	0 - 30 min	0 - 30 min	0 - 30 min
Automatic shut off	Yes	Yes	Yes
power level indicator display	Yes	Yes	Yes
Contact Monitor	Yes	Yes	Yes
Ultrasound Power Display	Yes	Yes	Unknown
NEUROMUSCULAR STIMULATION			
Output waveforms	Interferential Not applicable Not applicable	Interferential Medium Frequency Biphasic	Interferential
Treatment timer	1-30 minutes±1%	1-60 minutes±1%	1-30 minutes±1%
Automatic shut off	Yes	Yes	Yes
Current level indicator display	Yes	Yes	Yes
Number of output modes	1	3	1
Channel(s)	2	2	2
Synchronous or alternating output channels	Synchronous	Synchronous	Synchronous
Max Output Current (mA)	Interferential 0-65±10% mA RMS, max 500Ω - 65mA 2KΩ - 27mA 10KΩ - 1.6mA	Interferential 0-65±10% mA RMS, max 1Kohm load	Interferential 0-35±10% mA RMS, max 1Kohm load

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	N/A N/A N/A N/A	Premodulated and medium frequency modes 0-50±10% mA RMS, max 1Kohm load Biphasic mode 0-99±10% mA peak, max 1Kohm load High volt mode 0-2500±10% mA peak, max 1Kohm load Microamp mode 10-990±10 µA peak, 1Kohm load	
Max output Voltage (V)	Interferential 0-65v ±10% volts RMS 500Ω - 42.6V 2KΩ - 56V 10KΩ - 14.8V N/A N/A N/A N/A	Interferential 0-65±10% volts RMS, 1Kohm load Premodulated and medium frequency modes 0-50±10% volts RMS,1Kohm load Biphasic mode 99±10% volts peak, 1Kohm load High volt mode 0-500±10% volts peak,1Kohm load Microamp mode 1.0±10% volt peak, 1Kohm load	Interferential 0-36±30% volts RMS, 1Kohm load
Regulated current or regulated voltage	Regulated current	Regulated current	Regulated current
Electrode size	Round, 2 inch diameter	Round, 1.5, 2, and 3 inch diameter	Round 2 inch diameter
Maximum current density (2 inch dia)	3.2 mA/cm^2 at 500Ω 3.2 mA/cm^2 at 1kΩ 1.33 mA/cm^2 at 2kΩ 0.08 mA/cm^2 at 10kΩ	Unknown 3.2 mA/cm^2 at 1kΩ Unknown Unknown	Unknown Unknown Unknown Unknown

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Maximum power density	0.195 W/cm2 at 500kΩ ≤ 0.25 W/cm^2 0.208 W/cm2 at 1kΩ ≤ 0.25 W/cm^2 0.074 W/cm2 at 2kΩ ≤ 0.25 W/cm^2 0.0012 W/cm2 at 10kΩ ≤ 0.25 W/cm^2	Unknown 0.208 W/cm^2 at 1kΩ ≤ 0.25 W/cm^2 Unknown Unknown	Unknown Unknown Unknown Unknown
Compliance with 21 CFR 898	Yes	Yes	Yes
Electrode Housing materials and construction	No	No	No
Carrier frequency	4000 Hz	4000 Hz	4800 Hz
Interferential Frequency range	Channel 1=4000Hz Channel 2=4000 Hz to 4250 Hz ±1% (Interferential mode)	Channel 1=4000Hz Channel 2=4000 Hz to 4250 Hz ±1% (Interferential mode)	Channel 1=4800Hz Channel 2=4800Hz to 5050 Hz ±1% (Interferential mode)
Interferential beat frequency PPS	1 – 250 Hz in 5Hz increments	1-250 Hz depending on selected program	1-250 Hz depending on selected program
All Channels	Interferential N/A N/A	Interferential Medium Frequency Biphasic	Interferential
Output Displays	Two simultaneously, amber channel active indicators	Two simultaneously, amber channel active indicators	Two simultaneously, amber channel active indicators
Channel Isolation	Yes Transformer isolated	Yes	Yes
Automatic No Load Trip	Yes	Yes	Yes
Control Method	On/Off	On/Off or hold	On/Off or hold
Max Leakage Current (µA)	Chassis <100 Electrodes <100	Chassis <100 Electrodes <100	Chassis <100 Electrodes <100
Patient leakage current (µA)	Normal condition – 0.004 µA Single fault condition – 0.014 µA	Unknown	Unknown
Indicator Display Unit Functioning	Yes	Yes	Yes
Low Battery Indicator	N/A	N/A	N/A
Net charge (µC per pulse) at	0. Method of achieving zero net charge is Balanced Waveform	Unknown	Unknown

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500 Ω (if zero, state method of achieving zero net charge)			
Maximum phase charge (µC) at 500 Ω	8.9 µC	Unknown	Unknown
ON time	5 sec	5 sec 10 sec	Unknown
OFF time	30 sec	5 ,10, 30 ,50 sec	30 sec

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Discussion of Similarities and Differences between Subject BRH-A2 and Sonicator Plus 930 Predicate Device:

Based on aforementioned comparison chart the subject device is substantially equivalent to predicate device. Although there are differences in appearance, the Sonicator plus 930 and the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) system are comparable in what it provides in terms of treatment.

The following parameters are similar:

- User friendly interface, easy to operate
- Indicator Display Unit Functioning
- Operating and Storage Temperature and Humidity
- Ultrasound Frequencies
- Ultrasound mode (Continuous)
- Ultrasound Contact Monitor
- Ultrasound Beam type (Collimated)
- Ultrasound Timer range and automatic shut off
- Interferential waveform output parameters
- Power level indicator display

The following parameters are different:

- External appearance (Size and Weight)
- Ultrasound Maximum intensity
- Ultrasound Pulse mode
- Ultrasound treatment head dimensions
- Electrotherapy number of Output Waveforms
- Electrode size

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) System has the same intended use and similar characteristics as the predicate device, the Sonicator Plus ® 930.

Moreover, bench testing and non-clinical testing documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) System are substantially equivalent to the predicate devices.

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Discussion of Similarities and Differences between Subject BRH-A2 and DU857 Predicate Device:

Based on aforementioned comparison chart the subject device is substantially equivalent to reference predicate device. Although there are differences in appearance, the DU857 and the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) system are comparable in what it provides in terms of treatment.

The following parameters are similar:

- 4-pole interferential current therapy using a quadpolar electrode configuration
- User friendly interface, easy to operate
- Indicator Display Unit Functioning
- Ultrasound Frequencies
- Ultrasound mode (Continuous)
- Ultrasound Contact Monitor

The following parameters are different:

- Housing Materials
- Operating Temperature
- External appearance (Size and Weight)
- Humidity
- Storage Temperature
- Treatment Timer
- Transducer
- Maximum Output Power for Ultrasound
- Maximum Intensity for Ultrasound

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) System has the same intended use and similar characteristics as the reference predicate device, the DU857. Moreover, bench testing and non-clinical testing documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) System are substantially equivalent to the reference predicate devices.

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Performance testing:

Testing information demonstrating performance of BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) device in the intended environment of use is supported by testing that was conducted in accordance with FDA recognized standards as follows:

The following testing was conducted to prove safety and effectiveness as well as Substantial equivalence to the predicate devices:

Item	Test Name	Results
1	ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) "Medical electrical equipment. Part 1: General requirements for safety and essential performance"	Passed all testing requirements
2	IEC 60601-2-5:2009 Medical electrical equipment. Part 2-5: Particular requirements for the safety of ultrasonic-physiotherapy equipment"	Passed all testing requirements
3	IEC 60601-2-10 Edition 2.0 2012-06 "Medical electrical equipment. Part 2-10 Particular requirements for the safety and essential performance of nerve and muscle stimulators.	Passed all testing requirements
4	ISO 14971:2007 "Medical devices – Application of risk management to medical devices" including residual risks evaluation.	Passed all testing requirements
5	IEC 60601-1-6 Edition 3.1 2013-10 "Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability"	Passed all testing requirements
6	IEC 60601-1-8:2006 & A1:2012 "Medical electrical equipment. Part 1-8: General requirements for basic safety and essential performance– Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems"	Passed all testing requirements
7	IEC 60601-1-2: 2007 /AC: 2010 "Medical electrical equipment. Part 1-2: Electromagnetic compatibility – Requirements and tests"	Passed all testing requirements
8	IEC 62304 Edition 1.1 2015-06 "Medical Device Software Development"	Passed all testing requirements
9	ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes	Passed all testing requirements

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Conclusion:

The BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) has similar indications for use to the Sonicator predicate device and identical indications for use to the DU857 predicate with similar technological characteristics to both predicate devices. Any differences in the predicates' technological characteristics do not raise any new questions of safety or effectiveness. Thus, the BRH-A2 Combined Ultrasound and Electric Field Stimulation (CUSEFS) System is substantially equivalent to the predicate devices