DEC - 6 2013

K130978

SECTION 5. 510(k) SUMMARY

In accordance with the Safe Medical Devices Act of 1990 and the final rule concerning 510(k) Summaries published in the Federal Register on December 14, 1995, page 64287 (Vol. 59, No. 239), with an effective date of March 14, 1995, ZetrOZ has prepared this 510(k) Summary in compliance with 21 CFR Part 807.93 which is included below.

Date prepared: April 8th 2013

SECTION 5.1 REASON FOR SUBMISSION

The ZTX Ultrasonic Diathermy Device is a new device and ZetrOZ INC is therefore submitting a new 510(k) to FDA for clearance to market and distribute the device into interstate commerce in the United States of America.

SECTION 5.2 SUBMITTER/510(K) HOLDER

Name:	ZetrOZ, INC
Address:	56 Quarry Rd. Trumbull, CT 06611
Contact Person:	Dr. George K. Lewis, Jr.
Telephone:	888-202-9831 Ext. 700
Date Prepared:	April 8th 2013

SECTION 5.3 DEVICE NAME

Proprietary Name:	ZTX
Common/Usual Name:	Ultrasonic Diathermy device
Classification Name:	Ultrasonic Diathermy Device (21 CFR 890.5300)
Review Panel:	Physical Medicine
Product Code	IMI
Class:	II
Performance Standard:	21 CFR 1050.10 (April 1, 2012)

SECTION 5.4 INTENDED USE

ZTX is intended to supply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, muscle spasms, joint contractures, and increase local circulation.

The ZTX Ultrasonic Diathermy Device is a prescription use device. The ZTX Device should only be administered and monitored by a licensed healthcare practitioner.

SECTION 5.5 DEVICE DESCRIPTION OVERVIEW

Section 11 of this submission contains a detailed description of the ZTX Ultrasonic Diathermy Device. This section is intended as a brief introduction to the device.

The ZTX Ultrasonic Diathermy Device consists of a ZTX Ultrasound Power Controller and cable which can be used to power one or two ZTX Ultrasound Applicators simultaneously that each generate ultrasonic energy at one frequency (3 MHz) and one power setting (0.65 W) per ZTX Ultrasound Applicator. The ZTX Ultrasound Applicators are applied with one time use ZTX Ultrasound Coupling Bandages which hold the ZTX Ultrasound Applicators in place during treatment and allow for the transmission of ultrasound into the body. This provides the operator with the ability to use the device hands-free in a single applicator mode of operation that delivers 0.65W at 3MHz or in a dual applicator mode of operation that provides 1.3W at 3MHz. The ZTX Ultrasound Power Controller displays battery and treatment setting information to the operator and provides control of device treatment time. The ZTX Ultrasound Applicator frequency and power settings are not modifiable by the operator. The ZTX ultrasound applicators and coupling bandage allows for the delivery of ultrasonic energy to tissue at one or two locations simultaneously, as determined by a physician. The ZTX Ultrasound Power Controller , ZTX Ultrasound Applicators, interconnecting power cable and ZTX Ultrasound Coupling Bandages comprise the entire ZTX treatment system.

SECTION 5.6 PERFORMANCE TESTING

The ZTX Ultrasonic Diathermy Device was evaluated by ZetrOZ Inc. testing to the performance standards set forth under 21 CFR 1050.10 (April 1, 2012) for ultrasonic diathermy devices and demonstrated that all requirements were met (see Section 18). Third party verification testing of IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Version 2, 1988 + A1:1991 + A2:1995) and IEC 60601-1-2 Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility (Version 3, 2012) was conducted and showed that all requirements were met as described in forms 3654 for each standard cited (see Section 17). In a series of bench testing experiments, the ZTX Ultrasonic Diathermy Device demonstrated substantially equivalent diathermic heating effects on an ex vivo bovine muscle model (see Section 18). Additionally, bench verification testing was completed to demonstrate full adherence to the diathermy ultrasonic performance standard of 21 CFR 1050.10 (April 1, 2012) (see Section 18).

In a direct comparison to the predicate, the ZTX Ultrasonic Diathermy Device demonstrated substantially equivalent diathermy and safety profiles in a GLP structured in vivo swine model (see Section 19). The ZTX Ultrasonic Diathermy Device and ZTX Ultrasound Coupling Bandage demonstrated biocompatibility in sensitization, irritation, and cytotoxicity (see Section 15). Across all performance testing, the ZTX Ultrasonic Diathermy Device with ZTX Ultrasound Coupling Bandage was found to be as safe and effective as the predicate device

SECTION 5.7 SUBSTANTIAL EQUIVALENCE SUMMARY

5.7.1 Predicate Devices

The ZTX Ultrasound Diathermy Device is substantially equivalent to the METRON MEDICAL AUSTRALIA PTY LTD, ACCUSONIC ADVANTAGE (K120171). **Section 12** contains a detailed comparison of the ZTX Ultrasound Diathermy Device with the

predicate device. Below is the substantial equivalence table for the ZTX and Accusonic Advantage devices.

Table 5.1: Substantial equivalence table for ZTX and Accusonic Advantage Predicate.

Characteristic	ZTX	ACCUSONIC ADVANTAGE	COMPARISON
Classification Name	Ultrasonic Diathermy Device	Ultrasonic Diathermy Device	Identical
Service Type	Physical Medicine	Physical Medicine	Identical
	Therapeutic – Class II	Therapeutic – Class II	Identical
Product Code	IMI	IMI	Identical
Intended Use	To apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, joint contractures and increase local circulation (21 CFR 890. 5300).	To apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, joint contractures and increase local circulation (21 CFR 890. 5300).	Identical
Target Population	People suffering from joint and muscle conditions diagnosed by a physician	People suffering from joint and muscle conditions diagnosed by a physician	Identical
Output Channels	2 independent power channels	2 independent power channels	Identical
Number of Treatment Modes	2 discrete settings of power at the same frequency	450 discrete settings of ultrasound frequency, plus width, duty cycle and power	Different: ZTX has 2 preset output characteristics while the predicate has 450 different treatment modes As shown in Section 18 performance testing, ZTX treatment settings are substantially equivalent to two of the predicates treatment settings.
Frequency (Hz)	3MHz ± 20%	1.1MHz ± 20% & 3.3 MHz ± 20%	Different: ZTX operates at 3MHz, while the predicate device operates at both 1.1 MHz and 3.3 MHz

			The ZTX provides a subset of the performance of the predicate device and is still as safe and effective
Temporal Average Power for each Treatment Mode (Watts)	Single Applicator: At 3MHz: 0.65W ± 20% Dual Applicator: At 3MHz: 1.3W ± 20%	Single Applicator: At 1.1MHz: 0-12W± 20% in 0.5W increments At 3.3 MHz 0-7.5W± 20% in 0.5W increments	Different: ZTX provides a preset treatment while the predicate has a larger range of output powers. The ZTX provides a subset of the performance of the predicate device and is still as safe and effective
Duty Cycle	Continuous - 100% duty cycle	At 1.1MHz and 3.3 MHz: Continuous 100% duty cycle or Pulsed 10, 20%, and 50% duty cycle	Different: ZTX operates at 100% duty cycle while the predicate can operate at 10-100% duty cycle. The ZTX provides a subset of the performance of the predicate device and is still as safe and effective
Temporal Maximum Intensity (Watts per cm^2)	0.264 W/cm^2 ± 20%	At 1.1MHz: $3W/cm^2$ At 3.3MHz: $3W/cm^2$	Different: The ZTX Ultrasonic Diathermy Device has a lower maximum intensity The ZTX provides a lower maximum intensity but is still a subset of the performance of the predicate device and is still as safe and effective
Peak Power (Watts)	1.3W ± 20%	12W± 20%	Different: The ZTX Ultrasonic Diathermy Device has a lower maximum power The ZTX provides a

			subset of the performance of the predicate device and is still as safe and effective
Power Supply	120/240 VAC with 5V DC Input Power Jack and Battery Powered	120/240V AC Input Power Jack	Different: The ZTX operates in both DC and AC mode. The predicate device operates in AC mode only.
Maximum Battery Life	4 Hours	Not battery operated	Different: The ZTX is battery operated while the predicate is not. This does not affect the safety or efficacy of the device.
Maximum treatment timer setting	4 Hours	0.5 Hours	Different: The ZTX Ultrasonic Diathermy Device may be set to a longer treatment duration. As shown in Section 18 and 19 performance testing, ZTX treatment settings are identical to two of the predicates treatment settings and is substantially equivalent. Furthermore, both ZTX and predicate provide substantially equivalent heating and safety profiles.
Therapeutically Applied	Ultrasound Coupling Gel or Ultrasound Coupling Bandage	Ultrasound Coupling Gel or Water Bath	Different: The ZTX may be applied with a ZTX ultrasound coupling bandage
Beam Non Uniformity Ratio (BNR)	BNR: <5:1 ± 20%	BNR <5:1 ± 20%	Identical
Applicator Type	Up to two circular Applicators with 3 MHz output	Up to two circular Applicators with 1.1 MHz and 3.3 MHz capability	Different: The ZTX Ultrasonic Diathermy Device provides a single frequency output while the predicate provides two

Applicator Type Applicator Emitting Surface Areas (cm^2)	Up to two circular Applicators One Applicator : 5 cm^2 Two Applicators :10 cm^2	Up to two circular Applicators One Applicator : 5 cm^2 Two Applicators :10 cm^2	Identical
Effective Radiating Area (ERA)	One: 6 cm^2 Two:12 cm^2 ± 20%	One: 5 cm^2 Two:10 cm^2 ± 20%	Different: The ZTX provides a slightly larger ERA. This does not affect the safety or efficacy of the ZTX.
Beam Type	Diverging	Collimated	Different: The ZTX Ultrasound Applicator spreads the ultrasound field as the energy is delivered into the patient. This does not affect the safety or efficacy of the ZTX.
Piezo-Crystal Material	Lead Zirconate-Titanate	Lead Zirconate-Titanate	Identical
Coupling Bandage	ABS Plastic with integrated coupling medium	None	Different: The ZTX Ultrasonic Diathermy Device includes a coupling bandage while the predicate does not. This does not affect the safety or efficacy of the ZTX.
Applicator Lens Material	Ultem	Aluminum	Different: The ZTX Ultrasonic Diathermy Device is made from biocompatible plastic while the predicate is made from biocompatible aluminum. The different applicator materials do not affect the safety or efficacy of the ZTX.
Environmental – Operating Temperature Range	0°C to +50°C (32°F to +122°F)	0°C to +50°C (32°F-+122°F)	Identical
Performance Standards	21 CFR 1050.10	21 CFR 1050.10	Identical
Sterility	Non Sterile	Non Sterile	Identical
Designed to meet Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Identical

Power Controller Size	2.4 x 2.79 x 0.74 in	9.5 x 4.7 x 9.5 in	Different: The ZTX Ultrasonic Diathermy Device is smaller than the predicate device. This does not affect the safety or efficacy of the ZTX.
Individual Applicator Size	1.52 x 1.30 x 0.45 in	Aprox~1.6 in Diameter 5 in Length	Different: The ZTX Ultrasound Applicator is smaller than the predicate. This does not affect the safety or efficacy of the ZTX.
Biocompatibility	Yes	Yes	Identical
Mechanical safety	Yes	Yes	Identical
Radiation safety (if not radioactive state as such)	Not Radioactive	Not Radioactive	Identical
Software/Firmware	No	Yes: MODERATE LOC	Different: The ZTX Ultrasonic Diathermy Device does not include any software, unlike the predicate. This does not affect the safety or efficacy of the ZTX.

5.7.2 Summary

This pre-market notification demonstrates Substantial Equivalence of the ZetrOZ ZTX Ultrasound Diathermy Device to the predicate Accusonic Advantage as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

SECTION 5.8 SOFTWARE/FIRMWARE

The ZTX Ultrasonic Diathermy Device has no software or firmware and no volatile memory. The ZTX Ultrasonic Diathermy Device has no microprocessor, CPU or programmable device that changes or controls the functionality of the device.

However, there is an internal battery fuel gauge integrated circuit (IC) that requires data to be downloaded to the device's non-volatile memory during manufacturing to configure the IC to recognize the battery characteristics required for full and empty battery capacity detection. This commercially available IC has limited functions: it monitors the battery capacity, it drives the LED fuel level display, and prevents the setting of treatment time in excess of current battery capacity.

SECTION 5.9 LABELING OVERVIEW

5.9.1 Claims

ZetrOZ makes the following claims for the ZTX Ultrasonic Diathermy Device:

The ZTX Ultrasonic Diathermy Device will apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, joint contractures, and increase local circulation.

The ZTX Ultrasonic Diathermy Device is a prescription use device. The ZTX Device should only be administered and monitored by a licensed healthcare practitioner.

5.9.2 Labeling

Instructions for use, ZTX Ultrasound Power Controller labeling, ZTX Ultrasound Applicator labeling, ZTX Ultrasound Coupling Bandage labeling, and promotional literature are contained in **Section 13** of this submission.

SECTION 5.10 CONCLUSION

The ZTX Ultrasonic Diathermy Device intended use, and indications statement for use, are substantially equivalent to the previously cleared predicate device. Furthermore, the ZTX Ultrasonic Diathermy Device has the same intended use and target population as the predicate device. ZetrOZ has demonstrated through performance testing on the ZTX Ultrasonic Diathermy Device that it is substantially equivalent to the predicate device. This was shown in a series of bench testing, *in vivo* swine testing, contract laboratory biocompatibility testing, and verification and validation testing of the ZTX Ultrasonic Diathermy Device. The ZTX is a scaled down version of the predicate device with reduced number of modes and features compared to the predicate device. This however does not impact the intended therapeutic effect, safety, or effectiveness of the device when used as labeled. Therefore, the design, operation, and technical characteristics of the ZTX system are substantially equivalent to, and as safe and effective as, the predicate device.

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

December 6, 2013

ZetrOZ INC
George K. Lewis, Jr., PhD
Chief Scientific Officer
56 Quarry Road
Trumbull, CT 06611

Re: K130978
Trade/Device Name: ZTX Ultrasonic Diathermy Device
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: October 31, 2013
Received: November 4, 2013

Dear Dr. Lewis:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130978

Device Name: ZTX Ultrasonic Diathermy Device

Indications For Use:

The ZTX Ultrasonic Diathermy Device is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

The ZTX Ultrasonic Diathermy Device is a prescription use device. The ZTX Device should only be administered and monitored by a licensed healthcare practitioner.

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S