A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device "nonthermal shortwave therapy" (SWT), was published on October 13, 2015. See here: https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to

While the device submitted and cleared through K121338 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ivivi Health Sciences, LLC
% Ms. Kathryn Clubb
President & CEO
330 Townsend Street, Suite 100
San Francisco, California 94107

JUL 2 7 2012

Re: K121338
Trade/Device Name: Zeobi
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: Class III
Product Code: ILX
Dated: June 27, 2012
Received: June 29, 2012

Dear Ms. Clubb:

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 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/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,

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

Enclosure

4. Indications for Use Statement

Indications for Use
510(k) Number (if known): _____

Device Name: Zeobi

Indications for Use: Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121338

510(k) Summary

JUL 27 2012

Zeobi: Special 510k Summary

Submitter:	Ivivi Health Sciences LLC 330 Townsend Street, Suite 100 San Francisco, California 94510 Phone: 415-814-2460 Fax: 415-678-5137
Contact:	Kathryn Clubb President and CEO Office phone: 415-814-2460
Date Summary Prepared:	June 27, 2012
Device Trade Name:	Zeobi
Common Name:	Shortwave diathermy
Classification Name:	890.5290(b) Shortwave diathermy for use other than applying therapeutic deep heat
Product Code	ILX
Classification Code:	A shortwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues.
Equivalent Device:	SofPulse Torino II (K070541)
Device Description:	The Zeobi is a portable battery powered non-invasive therapy device which applies to the body electromagnetic energy at a radio frequency (RF) of 27.12 MHz for the treatment of medical conditions by means other than the generation of deep heat within body tissues, i.e., by athermal means. The Zeobi was designed to deposit mean radio frequency energy in tissue which is equivalent to that of the Torino II. The Zeobi delivers the RF signal to the tissue target via inductive coupling with an applicator coil. The device is portable and treatment can occur directly through dressings, clothing, casts, compression garments or supports.
Nonclinical Performance Data:	This Special 510(k) contains the risk assessment and a summary of verification/validation testing to support the three requested modifications.

Clinical Performance Data: Clinical data was not determined to be necessary to support the substantial equivalence for the three modifications requested in this Special 510(k).

Comparison:

Device Features	Predicate **Torino II** **K070541**	**Zeobi** **K121338**
Indications for Use:	Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue	Adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue
Carrier Frequency	27.12 MHz	27.12 MHz
Burst Duration	2 msec	2 msec
Burst Repetition	2 Hz	2 Hz
Energy Density	0.13 ± 0.02 μWs/cm^3	0.13 ± 0.02 μWs/cm^3
Electrical Safety	Conforms with IEC 60601-1	Conforms with IEC 60601-1
Electromagnetic safety	Conforms with IEC 60601-1-2	Conforms with IEC 60601-1-2
Power Supply	In-Circuit Battery Source: Primary Lithium Coin Cell Batteries (2)	Detachable Battery Pack: Primary Lithium Coin Cell Batteries (2)
User Display	LED Display with two green lights	Multi-Function LCD Display
Treatment Modes	• Automatic mode: 6 treatments per for three days, 3 treatments per day for 3 days and 2 treatments per day until shut off or battery depletes • Manual mode: user activated	• Automatic mode: 12 treatments every two hours until the unit is shut off or battery depletes • Manual mode: user activated
Treatment Time	Maximum of 30 minutes	Maximum of 15 minutes

Performance bench testing was performed on carrier frequency, burst duration, burst repetition and energy density (relative power measurement). Testing of carrier frequency, burst duration and burst repetition was done with a calibrated high frequency probe/oscilloscope system. For the energy density test measurement of power was performed in a validated saline load with a calibrated spectrum analyzer via a calibrated inline attenuator.

Standards Met:

- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2 Medical Electrical Equipment – Part 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests

Conclusion: The Zeobi is identical to the Torino II in terms of its indications for use and intended use.

The Zeobi is substantially equivalent to the Torino II in terms of technical specifications, operating performance features, and general design features.