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 K070541 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
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2008

Ivivi Technologies
% Andre DiMino
224 Pegasus Avenue.
Northvale, New Jersey 07647

Re: K070541
Trade Name: Ivivi Sofpulse, Models 912-M10, Roma3, and Torino II
Regulatory Class: III
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Product Code: ILX
Dated: November 6, 2008
Received: November 7, 2008

Dear Mr. DiMino:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark Melkerson, M.S. for
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070541

Device Name: Ivivi Sofpulse, Models 912-M10, Roma3, and Torino II

Indications For Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070541

K070541

Ivivi Technologies, Inc.
224-S Pegasus Avenue, Northvale, NJ 07647
201-784-8168 FAX 201-784-0620
www.ivivitechnologies.com

DEC 11 2008

Premarket Notification [510(k)] Summary

Date Prepared: December 9, 2008

Trade Name: Ivivi SofPulse: Models 912-M10, Roma^3 and Torino II

Common Name: Shortwave Diathermy

Classification Name: Shortwave diathermy for all other uses (per 21 CFR Section 890.5290(b)); Product Code ILX (Diathermy, shortwave, for use other than applying therapeutic deep heat)

Manufacturer's Name: IVIVI TECHNOLOGIES, INC.
Address: 224-S Pegasus Avenue
Northvale, New Jersey 07647

Corresponding Official: Mr. André DiMino
Title: Executive Vice President
Telephone: 201-767-6040
Fax: 201-784-0620

Predicate Device: MRT (K903675), Product Code: ILX (per 21 CFR Section 890.5290(b))

Device Description: SofPulse (912-M10, Roma^3 and Torino II) devices are shortwave diathermy medical devices which apply 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 SofPulse models were designed to deposit mean radio frequency energy in tissue which is equivalent to that of the predicate MRT device. All of the SofPulse options deliver the RF signal to the tissue target via inductive coupling with an applicator coil. SofPulse devices are portable and treatment can occur directly through dressings, clothing, casts, compression garments or supports.

Intended Use/Indications For Use: Adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

Technological Characteristics:

Device	MRT (K903675)	SofPulse (K070541)
Underlying Technology [ILX/890.5290(b)]	Deposit athermal RF energy in tissue	Deposit athermal RF energy in tissue
How Energy Deposited	Induction (coil applicator)	Induction (coil applicator)
Non-thermal	Yes	Yes
Risk	Low	Negligible (via Risk Analysis)
Carrier Frequency	27.12 MHz	27.12 MHz
Mean Duty Cycle	2.3%	2.5%
Energy Deposited Per Pulse	6.8 $\mu Ws/cm^3$	6.5 $\mu Ws/cm^3$
Treatment Duration	5 – 30 min	5 – 30 min
Battery/Mains Power	Mains only	Battery or Mains
Portable	Yes	Yes

The SofPulse models have the same intended use/indications for use and safety characteristics as the predicate device. Equivalence of performance of the SofPulse and MRT was demonstrated with bench testing in saline tissue equivalents and with an animal model validated for evaluation of pain and edema.