

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 K972093 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.



T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh Associates, Inc.
Representing Regenesis Biomedical, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

OCT 21 1997

Re: K972093
Trade Name: Regenesis Model 42
Regulatory Class: III
Product Code: ILX
Dated: June 3, 1997
Received: June 4, 1997

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

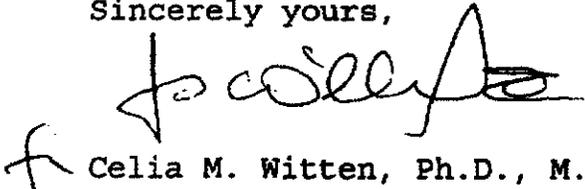
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic

GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

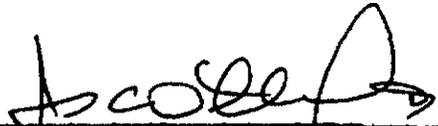
Device Name: Regenesis Model 42

Indications For Use:

The Regenesis Model 42 is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12972023

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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510(k) Summary

K972093
Oct. 21, 1997

Regenesis Model 42

Common/Classification Name: Shortwave Diathermy
21 CFR 890.5290(b), Class III

Regenesis Biomedical, Inc.
1435 North Hayden Road
Scottsdale, AZ 85257-3773

Contact: Mary C. Ritz, Ph.D.

Tel: 602-970-0645
FAX: 602-970-6355

Prepared: May 21, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The Regenesis Model 42 is substantially equivalent to the MRT® sofPulse™ shortwave diathermy device made by ElectroPharmacology (K903675), which was cleared on January 17, 1991.

B. DEVICE DESCRIPTION

The Regenesis Model 42 device is a pulsed short-wave diathermy device. The device has a solid state design that is very simple. It has no microprocessor and therefore no software.

The Regenesis Model 42 unit consists of a main control console connected by cable to a treatment pad. The pad and cable are a single unit which is connected or disconnected easily from the console. The pad surface is water proof, bacterial resistant and designed to be placed directly on the patient or on top of any standard dressings used over the area to be treated.

C. INTENDED USE

The Regenesis Model 42 is intended to be used in the palliative treatment of postoperative pain and edema in superficial soft tissue.

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D. SUBSTANTIAL EQUIVALENCE SUMMARY

The new device has the same indications statement as the predicate device and it has the same technological characteristics. Some of the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, in addition to a side-by-side comparison of the descriptive characteristics of the **Regenesis Model 42** and the predicate device, performance data were presented which assure equivalence. The 510(k) decision algorithm brings us to a determination of Substantial Equivalence, as defined in the Federal Food, Drug, and Cosmetic Act.

E. TECHNOLOGICAL CHARACTERISTICS

See Section B, above.

F. TESTING

Amethyst Technologies carried out testing on the **Regenesis Model 42** to address the following issues: (1) electrical safety; (2) electromagnetic compatibility, (3) stray radiation, (4) and applicator field patterns. The results of all these tests support the substantial equivalence of the device.

G. CONCLUSIONS

Regenesis Biomedical has demonstrated through its comparison of characteristics with the predicate device and comparison of performance testing with the predicate device that the **Regenesis Model 42** is substantially equivalent to the predicate devices.

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