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 K131979 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 Center – WO66-G609
Silver Spring, MD 20993-0002

December 13, 2013

Regenesis Biomedical, Inc.
Richard Isenberg, MD
5301 North Pima Road, Suite 150
Scottsdale, Arizona 85250

Re: K131979
Trade/Device Name: Provant Therapy System, Model 4201
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class III
Product Code: ILX
Dated: November 8, 2013
Received: November 12, 2013

Dear Dr. Isenberg:

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): K131979

Device Name: **Provant Therapy System**

Indications For Use:

The Provant Therapy System is indicated for adjunctive use in the palliative treatment of postoperative 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 THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S

DEC 13 2013

K131979

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Regenesis Biomedical, Inc.
Contact Person	Richard Isenberg 5301 North Pima Road, Suite 150 Scottsdale, AZ 85275 (877) 970-4970
Date Prepared	27 June 2013
Product Name	Provant Therapy System
Common Name	Nonthermal shortwave diathermy device
Device Classification	Class III
Product Code	ILX
Predicate Device(s)	Provant System, Model 4201 (K091791)
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act.
Indications for Use	The Provant Therapy System is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.
Device Description	The Provant Therapy System is nearly identical to the previously cleared Provant System Model 4201 (cleared under K091791), except for the device labeling. Specifically, unlike the Provant System Model 4201, the Provant Therapy System does not include a contraindication for use in patients with metal implants. The device includes a Control Unit and Treatment Applicator. Disposable Applicator Covers are provided for the Treatment Applicator for infection control and to provide appropriate contact surfaces for the patient. The Control Unit for the Provant Therapy System is housed

	in a UL-compliant injection-molded case made of high-impact ABS plastic. The case contains a lockable hinge to prevent accidental closure of the lid. Upon opening the Provant Therapy case, the user sees the control panel of the Control Unit. The main electronics of the Control Unit are housed beneath its control panel. The device also includes a Treatment Applicator that is attached to the Control Unit. When not in use, the Treatment Applicator is stored inside the carrying case. The Treatment Applicator is removed from the case prior to administration of therapy, inserted into a Disposable Applicator Cover, and placed directly over the area to be treated. Device labeling is also located inside the case cover. Four pre-drilled holes in the underside of the case allow for attachment of the device to the optional roller stand (sold separately). The Disposable Applicator Covers of the Provant Therapy System are single-use-only and are intended to minimize contagion and help protect the Treatment Applicator from biological contamination. The Disposable Applicator Covers contain a Radio Frequency Identification Device (RFID) tag which guards against reuse of used Disposable Applicator Covers.
Technological Characteristics	Both the Provant Therapy System and the predicate device use shortwave radiofrequency energy in the FCC-approved ISM (Industrial, Scientific and Medical) frequency of 27.12MHz to provide treatment. The proposed Provant Therapy System has the same features and technological characteristics as the predicate Provant System Model 4201. Specifically, both the Provant Therapy System and the predicate device: • Emit pulsed radiofrequency energy at 1 kHz with a pulse width of 42µsec, resulting in a 4% duty cycle. • Emit an Electrical Field strength of 591 V/m at 5cm above the Treatment Applicator. • Provide an average RF Generator power of 1.9Watts • Utilize an identical 115V, 60Hz AC power source • Have a Voltage Standing Wave Ratio (VSWR) of 1.3:1 or less
Nonclinical Performance	The Provant Therapy System was tested using a validated tissue phantom with a variety of metal implants of different sizes, shapes and materials under worst case conditions (no dissipation of heat from circulation). No clinically significant rise in temperature of metal implants was noted. Retrospective analysis of the FDA MDR/MAUDE database, Regenesis and other industry complaint data from over 175,000 patients and over

	3,000,000 treatments, and the medical literature demonstrates that heating from implanted metal is a theoretical risk with no actual reported adverse events. This information further supports removal of the metal implant contraindication and that use of the Provant Therapy without this contraindication is as safe and as effective as use of the predicate Provant System Model 4201.
Conclusion	The Provant Therapy System and its predicate device have the same intended use, similar indications for use, and the same technological characteristics. The results of the analysis of the adverse event data, clinical literature and bench testing provide evidence that removal of the contraindication for use in patients with implanted metal in the area of treatment does not raise any new questions of safety and effectiveness as compared to the predicate device. Thus, the Provant Therapy System is substantially equivalent to its predicate device.