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

Rhausler, Incorporated
% Ms. Dionicia Reblando
Regulatory Consultant
837 Industrial Road, Unit E
San Carlos, California 94070

November 19, 2015

Re: K150455
Trade/Device Name: RT² Trabeculite Titanium Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 21, 2015
Received: October 23, 2015

Dear Ms. Reblando:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150455

Device Name
RT² Trabeculite Titanium Cervical Cage System

Indications for Use *(Describe)*

The Rhausler RT² Trabeculite Titanium Cervical Cage System is intended for spinal fusion procedures at one level (C3-T1) in skeletally mature patients with cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be implanted via an open, anterior approach and packed with autogenous bone. This device is to be used in patients who have at least 6 weeks of nonoperative treatment.

This device is intended to be used with supplemental spinal fixation systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

Assigned 510(k) number:	K150455
Company:	Rhausler Inc. 837 Industrial Road, Unit E San Carlos, CA 94070 USA Phone: 650-631-4515 Fax: 650-631-4555
Contact:	Dionicia B. Reblando Email: joann.reblando@yahoo.com
Date Prepared:	October 17, 2015
Proprietary Names:	RT² Trabeculite Titanium Cervical Cage System
Classification Name:	Intervertebral body fusion device
Classification:	21 CFR 888.3080, Class II, Product Code ODP
Predicate Device:	Primary predicate device-Nubic and Rabea Device (K082848) Interbody Fusion device with bone graft, cervical. Other predicate device: The Rhausler Plage Anterior Cervical Fusion System (K111272)
Device Description:	The Rhausler RT² Trabeculite Titanium Cervical Cage System is a cervical intervertebral body fusion device. The system is comprised of implants and instruments. The instruments are utilized for the implantation procedure. All implants are manufactured from medical grade Titanium alloy (Ti6 Al 4V). The implant is rectangular in shape with lordotic configuration, i.e., with 4 degree profiles. It is offered in two cross sectional sizes and is available in various height options to accommodate variations in patient anatomy. The center of the implant has a hollow cylindrical shape fenestration for placement of autogenous bone. Trabeculite Titanium Cervical Cage implant is provided sterile.
Indications For Use:	The Rhausler RT² Trabeculite Titanium Cervical Cage System is intended for spinal fusion procedures at one level (C3-T1) in skeletally mature patients with cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be

implanted via an open, anterior approach and packed with autogenous bone. This device is to be used in patients who have at least 6 weeks of nonoperative treatment.

This device is intended to be used with supplemental spinal fixation systems.

Technological Comparison to Predicate Device:

The Rhausler RT² Trabeculite Titanium Cervical Cage System is equivalent to the predicate devices. Both are intervertebral body fusion devices that attach to the anterior portion of the cervical spine during the development of spinal fusion. Additionally, both use the same fundamental scientific technology, principle of operation, and materials. Performance test results confirm that design differences do not pose new issues of safety or effectiveness.

Performance Testing:

Mechanical testing has been performed on the RT² Trabeculite Titanium Cervical Cage System in accordance to the FDA recommendation entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", which included Compression tests (Static and Dynamic) and Torsion tests (Static and Dynamic) per ASTM F2077-11, Subsidence testing per ASTM F2267-04 and Expulsion test. The results of testing and analyses conducted, demonstrate that the proposed system adequately meets the predetermined requirements established for its mechanical performance.

Biocompatibility tests for the RT² Trabeculite Titanium Cervical Cage were selected in accordance with blue book memorandum G95-1 entitled Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing". Biocompatibility tests were conducted in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR 58. All tests conducted passed biocompatibility requirements.

Sterilization validation of the RT² Trabeculite Titanium Cervical Cage implant is to be based on the requirements of ANSI/AAMI/ISO 11137-1:2006 (R) 2010 and 11137-2:2013 with a minimum Sterility Assurance Level of $1X10^{-6}$

Conclusion:

Based upon the design, technology, performance, and intended use, the Rhausler RT² Trabeculite Titanium Cervical Cage System is substantially equivalent to the predicate device/s currently marketed under the Food, Drug and Cosmetic Act.