DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 15, 2015

Rhondium Ltd.
c/o Mr. Kevin A. Thomas
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego California, 92130

Re: K143694
Trade/Device Name: Rhondium One-Visit-Crown (OVC)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 14, 2015
Received: April 15, 2015

Dear Mr. Thomas:

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,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*

K143694

Device Name

Rhondium One-Visit-Crown (OVC)

Indications for Use *(Describe)*

Rhondium One-Visit-Crown is intended for restoration of permanent teeth with a single unit crown.

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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510(k) Summary

Rhondium, Ltd

Rhondium One-Visit-Crown (OVC)

K143694

May 11, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	Rhondium, Ltd 4 Sheffield Street Katikati, 3129, New Zealand Telephone: +64 7 549 5566 Fax: +64 7 549 1461
Official Contact	Greer Fricker R&D Projects and Regulatory Manager
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Rhondium One-Visit-Crown (OVC)
Common Name	Dental material, filling/restorative, polymer based
Classification Name	Tooth Shade Resin Material
Classification Regulations	21 CFR 872.3690, Class II
Product Code	EBF
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Device Branch

INTENDED USE

Rhondium One-Visit-Crown is intended for restoration of permanent teeth with a single unit crown.

DEVICE DESCRIPTION

Rhondium One-Visit-Crown (OVC) is a hybrid ceramic crown consisting of a fully-cured anatomical occlusal layer and an uncured sub-layer that allows customization of the OVC to the tooth preparation. When finished, the customized OVC is bonded to a prepared natural tooth. The OVC is for restoring structurally compromised posterior teeth in cases normally restored with an onlay or a partial crown in a single dental visit. The OVC is selected based on tooth location and size and therefore no impressions are necessary. The OVC is provided in designs for the upper and lower first and second premolars and the first and second molars, and each design is provided in six (6) sizes (extra-small (XS), small (S), medium (M), large (L), extra-large (XL), and extra-extra-large (XXL)). The OVC is made from a ceramic tooth shade resin material, and is provided nonsterile for single use only.

Accessories to the OVC Device include the OVC Replica, an exact replica of the cured (occlusal layer) portion of the OVC. The OVC Replica is used to confirm that sufficient occlusal clearance was obtained during tooth preparation and to provide direct visualization of the overall 3D position of the OVC on the prepared tooth and the relationship with adjacent and opposing dentition. The OVC Replica is manufactured from vinyl polysiloxane impression material. OVC Wedges are accessories provided in four configurations (small left, small right, large left and large right), and are placed interproximally to create a working surface and to block out undercuts of the preparation. The Wedges are manufactured from polyacetal resin. The Selector Keys are accessories that allow the clinician to measure the mesial-distal distance in order to choose the appropriate size OVC for the restoration, and are used during the curing of the uncured resin to prevent disturbing the placement of the crown. The Selector Keys are manufactured from polycarbonate resin. All accessories are provided nonsterile for single use only.

PERFORMANCE DATA

Performance testing to demonstrate substantial equivalence included methods described in the following standards: ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*; ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*; ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*; and ISO 4049 *Dentistry – Polymer-Based Restorative Materials*. Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: product shelf life testing, biocompatibility testing, flexural strength testing, static compressive strength testing, and resin depth of cure testing. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

Rhondium, Ltd submits the following information in this Premarket Notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K072733, 3M™ ESPE™ Adult Crown, 3M ESPE Dental Products;

K050401, Ceramage, ShoFu Dental Corporation;

K052501, Resin Tooth Bonding Agent, Cosmedent, Incorporated; and

K092319, Star VPS, First Half, First Quarter, Danville Materials, Incorporated.

The primary predicate device is K072733. A comparison of the technological characteristics of the subject device and the predicate device K072733 is provided in the following table.

	Subject Device	**Predicate Device**
Comparison	Rhondium Ltd One-Visit-Crown (OVC) K143694	3M ESPE Dental Products 3M™ ESPE™ Adult Crown K072733
Crown Description	Preformed single tooth crown for one visit restoration	Preformed single tooth crown for one visit restoration
Teeth to be Restored	Upper and lower premolars and molars	Upper and lower canines, premolars, and molars
Specific Crown Designs	N=8 designs : Upper Premolar, Upper Molar, Lower Premolar, Lower Molar Each in Left and Right designs	N=5 designs Canine, Upper Premolar, Upper Molar, Lower Premolar; Lower Molar
Crown Sizes	Each design provided in 6 sizes: XS, S, M, L, XL, XXL	Each design provided in 2 sizes, except Lower Premolar (1 size)
Crown Material	Light-cured polymer composite resin	Light-cured composite
Crown Try-in (Trial) Material	OVC Replica Vinyl polysiloxane	None
Sizing Device Material	OVC Selector Key Polycarbonate	3M ESPE Crown Size Tool Material not stated
Other Accessory	OVC Wedges polyacetal resin	None

The subject device and the predicate device K072733 have the same intended use and very similar indications for use (restoration of permanent teeth with a single unit crown). The subject device and the predicate K072733 are provided in a range of designs and sizes to restore the premolars and molars of the upper and lower jaw. The subject device and the predicate K072733 encompass similar ranges of physical dimensions and characteristics, including design and dimensions, and both are made of light-cured resin materials. The subject device and the predicate devices are provided nonsterile for single use only.

The subject device consists of a fully-cured layer of tooth shade resin, a bonding layer, and a layer of uncured tooth shade resin to allow for customization and to assist with a cohesive fit of the crown to the prepared tooth.

Any differences in the technological characteristics between the subject device and the predicate devices do not affect substantial equivalence.

CONCLUSION

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.