DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 19, 2016

Adamant Co., Ltd.
% Deborah Grayeski
Sr. Project Manager
M Squared Associates
575 Eighth Ave, Suite 1212
New York, New York 10018

Re: K160203
Trade/Device Name: ADAMANT ZIRCONIA DISC
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 14, 2016
Received: September 15, 2016

Dear Deborah Grayeski:

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 801and Part 809); 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 and Part 809), 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" (21 CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K160203

Device Name
ADAMANT ZIRCONIA DISC

Indications for Use *(Describe)*

Dental ceramic restorations made from ADAMANT ZIRCONIA DISC are indicated for crowns and multi-unit bridges (up to a maximum of three elements). Applications include both anterior and posterior regions.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Number: K160203

510(k) Summary

In accordance with 21 CFR 807.92, the following summary of information is provided:

Sponsor: Adamant Co., Ltd.
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Date prepared: October 18, 2016

Regulatory Class: Class II

Proprietary Name: ADAMANT ZIRCONIA DISC

Common Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use

Regulation Number: 21 CFR 872.6660

Product Codes: EIH

Predicate Devices: Cercon® Base, K051462

DD cubeX^2 *,* K150196

Indication for Use:

Dental ceramic restorations made from ADAMANT ZIRCONIA DISC are indicated for crowns and multi-unit bridges (up to a maximum of three elements). Applications include both anterior and posterior regions.

Device Description:

The ADAMANT ZIRCONIA DISC is a ceramic block, composed of partially sintered yttria (yttrium oxide) stabilized zirconia (zirconium oxide) (Y-TZP) that can be cut/milled for forming dental restorations such as crowns and bridges (up to a maximum of three elements). Applications include both anterior and posterior regions. The ADAMANT ZIRCONIA DISC is designed for milled production on commercial CAD/CAM systems. After milling the disc, it is final sintered, so the Zirconia Disc is transformed into the

object as dental restorations.

Principle of Operation:

ADAMANT ZIRCONIA DISC is derived from zirconia powder (zirconium oxide) that has been processed through molding and sintering into three different shapes.

a) Disc shape having groove around periphery.
b) Disc shape without groove
c) Rectangular solid

Using commercially available CAD/CAM systems, these blanks are then further fabricated into various prosthetic dental devices, such as crowns and bridges. The dental restoration is then fired (i.e., sintered) in the oven to harden the ZrO2 so that its final properties can be achieved. All prosthetic dental devices are intended for single use applications.

ADAMANT ZIRCONIA DISC is supplied in different colors originating from the different constituent of color additives; and different translucencies originate from small differences in the amount of $Y_2 O_3$. Finally, the restorations may be color shaded following the CAD/CAM process.

The performance of formed zirconia dental blanks conforms to ISO 6872, Dentistry, Ceramic Materials.

Technological Characteristics Summary:

ADAMANT ZIRCONIA DISC is an oxide-based ceramic devices composed of partially sintered yttria stabilized zirconia powder indicated for dental restorations, such as crowns and bridges. The components of the ADAMANT ZIRCONIA DISC have been used in previously marketed devices and have been found safe for dental use. The data provided support the substantial equivalence of the subject device to the predicate devices for the indicated uses.

Technological Comparison with the Predicate Devices:

The following table shows similarities and differences of use, design, and material between the subject device and the predicate devices. The predicates were chosen based upon their material composition, indications for use, and physical characteristics.

Attribute	Subject Device	Predicate Devices		Comments
Trade Name	**Adamant ZIRCONIA DISC**	**CERCON BASE**	**Dental Direkt cubeX²**	N/A
510(k) Number	K160203	K051462	K150196	N/A
Device Description	The ADAMANT ZIRCONIA DISC is a ceramic block, composed of partially sintered yttria (yttrium oxide) stabilized zirconia (zirconium oxide) (Y-TZP) that can be cut/milled for forming dental restorations such as crowns and bridges (up to a maximum of three elements). Applications include both anterior and posterior regions. The ADAMANT ZIRCONIA DISC is designed for milled production on commercial CAD/CAM systems. After milling the disc, it is final sintered, so the Zirconia Disc is transformed into the object as dental restorations.	CERCON® BASE is a dense ceramic composed of partially sintered yttria (yttrium oxide) stabilized zirconia (zirconium oxide) powder (Y-TZP). It is processed in the dental laboratory by machining from a partially sintered Y-TZP blank which is then sintered to near full density and then finally veneered with a dental veneering ceramic. It is designed for anterior and posterior locations as a substructure (framework) for single tooth or bridge type restorations. CERCON® BASE is essentially equivalent to other Y-TZP products currently in the market.	*DD cubeX2* is a semi-finished dental blank made of yttrium stabilized pre-sintered zirconium dioxide, which has a super high translucency. The ceramics is of type II (not powder), Class 5 according to DIN EN ISO 6872 (FDA Recognition Number 4-178). The *DD cubeX2* dental blanks are designed for milled production of crowns and bridge frameworks on commercial CAD/CAM systems or hand-operated copy milling machines.	Same, with the exception that the Adamant Zirconia Disc is classified as Class 1, 2 and 3 (according to ISO 6872).
Regulatory Class	Class II	Class II	Class II	Same
Intended Use	Dental ceramic restorations made from ADAMANT ZIRCONIA DISC are indicated for crowns and multi-unit bridges (up to a maximum of three elements). Applications include both anterior and posterior regions.	CERCON® BASE is indicated for crowns, multi-unit bridges, and inlay bridges. Applications include both anterior and posterior regions.	Dental blanks made from *DD cubeX2* are indicated for crowns, multi-unit bridges (up to a maximum of three elements) and inlay bridges. Applications include both, anterior and posterior bridges.	Same, with the exception that the subject device is not intended for inlay bridges.
Multi-unit bridges	Up to a maximum of three elements.	Multi-unit bridges (with no more than two pontics between abutment crowns)	Up to a maximum of three elements.	Same as K150196
Chemical Composition [Units]				
$ZrO_2 + HfO_2 + Y_2O_3$ [wt%]	≥ 99.0	≥ 99.0	≥ 99.0	Same
HfO_2 [wt%]	≤ 5	≤ 2	ca. 0.2	Minor differences in additives result in the availability of different colors and translucencies.
Y_2O_3 [wt%]	≤ 10	≤ 5	< 10	
Al_2O_3 [wt%]	≤ 5	≤ 1	< 0.1	
Other oxides	≤ 5	≤ 1	≤ 0.05	
Sterile	Non-sterile	Non-sterile	Non-sterile	Same

ISO 6872 Categorization	Type II, Class 1, 2 and 3 (as the product is not intended for substructure)	Type II, Class 6	Type II, Class 5 due to restriction to 3-element restorations	Same Type, but different Class, as the Adamant Zirconia Disc is not intended for substructure, although its technological characteristics would support such use. Therefore, substantial equivalence is not affected.
Bending/Flexural Strength [MPa]	515 MPa – 1349 MPa	1200 MPa	>720 MPa	Depending upon the color variant of the Adamant Zirconia Disc, the flexural strength ranges from 515 MPa to 1349 MPa. The low-end range of flexural strength is mitigated by limitations set forth in labeling as per ISO 6872.
Density (after sintering) [g/cm3]	6.04 ~ 6.33 g/cm^3	Unknown	> 6.0	Same
Biocompatibility	ISO 10993	ISO 10993	ISO 10993	Same
Physical Testing	ISO 6872	ISO 6872	ISO 6872	Same

Performance Data (Non-Clinical):

Non-clinical testing was performed as follows.

Biocompatibility Test Performed	Result
Cytotoxicity test: Colony formation cytotoxicity test	Passed. No cytotoxic effect.
Intracutaneous reactivity in rabbits	Passed. Met test requirements.
Skin Sensitization Study in the Guinea Pig (Maximization Method)	Passed. No skin sensitization produced.
Genotoxicity: Bacterial Reverse Mutation Study	Passed. Test article extracts nonmutagenic.
Test results according to Requirements of ISO 6872	**Result**
Uniformity of the material	Passed
Freedom from extraneous materials	Passed
Physical and chemical properties: Activity concentration of uranium 238	Passed
Physical and chemical properties: Thermal expansion coefficient	Passed
Physical and chemical properties: Flexural Strength	Passed
Physical and chemical properties: Chemical solubility	Passed

Applicable Standards:

- ISO 10993-1, 10993-5, 10993-10, Biological evaluation of medical devices
- ISO 6872:2008, Dentistry – Ceramic materials

Substantial Equivalence Conclusion:

Both the subject and predicate devices are oxide-based ceramic devices composed of partially sintered yttria stabilized zirconia powder indicated for dental restorations, such as crowns and bridges. Both the subject and predicate devices have similar chemical compositions and physical characteristics. Data, including bench and biocompatibility test results, is provided to assess the effects of any technological differences between the subject device and the predicate. These data demonstrate that the device performs as intended and support a finding of substantial equivalence.