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

AMS
% Ho Dong Yang
CEO
Onbix Corporation
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Seoul, 135768 REPUBLIC OF KOREA

May 26, 2017

Re: K163238
Trade/Device Name: Eclipse Kiss Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 31, 2017
Received: February 6, 2017

Dear Ho Dong Yang:
This letter corrects our substantially equivalent letter of May 4, 2017.

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 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,

Mary S. Runner -S

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

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K163238

Device Name
Eclipse Kiss Zirconia

Indications for Use *(Describe)*
This device is a ceramic-based material that is used for prefabricated and patient-matched dental restorations such as inlays, artificial teeth, crowns, or bridges (up to maximum three-unit bridges) and processed by dental CAD/CAM.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: AMS
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Date Summary Prepared: Nov 14, 2016

Device Information:

Trade Name(s):	**Eclipse Kiss Zirconia**
Classification Name:	dental porcelain
Panel:	dental
Product Code & Regulation:	EIH / 872.6660

Predicate Device Information:
K150196 / DD Cubex2

Device Description:
The Eclipse Kiss Zirconia Dental Material is an integrated system of dental ceramic which support dental restorations and which are milled into prosthetic devices such as Crowns, Bridges, and Copings for partial and fully edentulous patients. The material can be milled into a variety of dental restorations to meet the specific needs of individual dental patients. Each patient is named by a physician or dentists written prescription specifying the type of restoration to be produced.
Eclipse Kiss Zirconia is intended to be used as a biocompatible material to be milled into precise customized dental restoration units for either crowns, copings or bridges (up to maximum three unit bridges); which may be further processed by the addition of ceramic layering to create aesthetic lifelike restorations.
Eclipse Kiss Zirconia is intended to be used as prescribed by a qualified and licensed physician or dentist by a written prescription which names the patient for which each individual dental restoration is to be produced.

Intended Use:
This device is a ceramic based material (porcelain) that is used for prefabricated and patient-matched dental restorations such as inlays, artificial teeth, crowns, or bridges (up to maximum three unit bridges) and processed by dental CAD/CAM

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

Performance properties
The device was conducted in compliance with the following Standard

ISO 10993 biological evaluation of medical devices

Summary of the technological characteristics compared to the predicate device
Eclipse Kiss Zirconia is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table provided below

Comparison table is as follows

	Eclipse Kiss Zirconia	**DD Cubex2**
Manufacturer	AMS	Dental Direkt Gmbh
510(k) Number	not yet assigned	K150196
Product code	EIH	EIH
Regulation number	872.6660	872.6660
Indications for use	Ceramic based material (porcelain) that is used for prefabricated and patient-matched dental restorations such as inlays, artificial teeth, crowns or bridges (up to maximum three unit bridges)and processed by dental CAD/CAM	Dental blanks made from DD cubeX^2 are indicated for crowns, multi-unit bridges (up to a maximum of three elements) and inlay bridges. Applications include both, anterior and posterior bridges.
Chemical composition	ZrO2+HfO2+Y2O3 ≥ 99 wt% Y2O3 < 10 wt% Fe2O3 ≤ 0.0002 wt%1 NiO ≤ 0.00008 wt%	ZrO2+HfO2+Y2O3 ≥ 99 wt% Y2O3 < 10 wt% HfO2 < 0.2 wt% Al2)3 < 0.1 wt%
shape	Blocks, disks	Disks
Colour	White	White
sterility	Non-sterile	Non-sterile
Sintering temperature	1450 ^{o}C	1450 ^{o}C
Performance properties	Flexural strength [MPa] ~ 749 Density [g/cm^3] > 6.0 Coefficient of thermal expansion [$10^{-6}K^{-1}$]: 10.3	Flexural strength [MPa] > 720 Density [g/cm^3] > 6.0 Coefficient of thermal expansion [$10^{-6}K^{-1}$]: 10
Biocompatibility	Suitable	Suitable

Non-Clinical Study performance
Not applicable

Conclusion
Eclipse Kiss Zirconia is substantially equivalent to the predicate device in its intended use and technological characteristics