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

June 26, 2015

Doceram Medical Ceramics GmbH
Mr. Stefan Drude
Head of Regulatory Affairs
Hesslingsweg 65-67,
Dortmund 44309
GERMANY

Re: K143071
Trade/Device Name: Nacera Pearl
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 7, 2015
Received: May 11, 2015

Dear Mr. Drude:

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" (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,

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

DOCERAM®
MEDICAL CERAMICS

Indications for Use

510(k) Number (if known): K143071

Device Name: **Nacera Pearl**

Indications For Use:

Nacera Pearl blanks are indicated for the fabrication of single crowns and bridgework:

- fully anatomical single crowns and bridgework (FCZ)
- Partially veneered or fully veneered crowns and bridges
- Inlays, onlays, and Maryland bridges
- Primary telescopic crowns

for anterior and posterior applications

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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Certified Company
DIN EN ISO 13485
für Medizinprodukte

510[k] Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92

Submitter Name	DOCERAM Medical Ceramics GmbH	
Submitter Address	Hesslingsweg.65-67, D – 44309 Dortmund	
Phone Number	+49-231-925025952	
Fax Number	+49-231-92566870	
Contact Person	Stefan Drude	
Date summary was prepared	July 10, 2014	
Device Trade Name(s)	Nacera Pearl	
Classification Name	Porcelain Powder for Clinical Use	
C.D.R. section number	872.6660	
Product Code	EIH	
Regulatory Class	class II	
Predicate Devices	K080195	Nacera Z, Nacera Z Medium
	K132102	BeCe CAD Zirkon HT+
	K133213	StarCeram Z-Med
	K117210	ZENO Zr Disc

Device Description

The devices covered by this submission are milling blanks for the fabrication of custom-made all-ceramic dental restoration

The devices are manufactured from yttria-stabilized tetragonal zirconia (Y-TZP) complying with all applicable requirements of ISO 6872 (dental ceramics) and all requirements of ISO 13356 (ceramic materials for implants for surgery).

They are provided in a partially sintered (pre-sintered) state

They are intended to be used by dental professionals e.g. dental technicians, for the fabrication of custom-made restorations for the sole use of a particular patient.

These restorations are designed virtually by dental technicians using the CAD technology on the basis of intraoral scans or scans from impressions and/or models.

The designed restorations are to be machined in all appropriate CAM Milling Centers out of **Nacera Pearl** blanks and finally sintered to full density.

On basis of the available shades the finished restorations, sintered to full density, may be used as full-contour, all-ceramic prosthesis or may be veneered with suitable dental porcelains using the layering technique. Telescopic primary crowns will not be veneered.

Nacera Pearl blanks are available in various shapes and dimensions such as discs, cylinders, bars, cubes, or other required forms, in order to meet the specifications of the different CAD/CAM milling machines used to generate the desired dental restorations,.

Nacera Pearl blanks are available in various shades in order to correspond to the different natural teeth colors and have a closer appearance to a natural tooth

Indications for Use

Nacera Pearl blanks are indicated for the fabrication of single crowns and bridgework:

- fully anatomical single crowns and bridgework (FCZ)
- Partially veneered or fully veneered crowns and bridges
- Inlays, onlays, and Maryland bridges
- Primary telescopic crowns

for anterior and posterior applications

Comparison of Indications for Use

Device name	Intended Use
Doceram Medical Ceramics Nacera Pearl	Fabrication of all-ceramics custom-made restorations for the sole use of particular patients. It is recommended for: ➢ fully anatomical single crowns and bridgework (FCZ) ➢ Partially veneered or fully veneered crowns and bridges ➢ Inlay, onlays, and Maryland bridges ➢ Primary telescopic crowns ➢ for anterior and posterior segment restorations
Doceram Medical Ceramics Nacera Z / Z Medium	Nacera Z and Nacera Z Medium is specially designed for use as framework (substructure) for dental restorations, single tooth or bridge type application at anterior and posterior locations. It is prepared for machining by use of CAM-techniques.
H.C. Starck StarCeram ® Z-Med	Fabrication of ➢ crowns, ➢ multi-unit bridges, ➢ inlay bridges ➢ all- ceramic restorations. applications include both anterior and posterior bridges

BEGO BeCe CAD Zirkon HT+	Fabrication of all-ceramics custom-made restorations for the sole use of particular patients. It is recommended for: ➢ fully anatomical single crowns and bridgework (FCZ) ➢ Partially veneered or fully veneered crowns and bridges ➢ Dentin core crowns and bridges ➢ Maryland bridges ➢ Telescopic crowns (primary part)
Wieland ZENO Zr	Fabrication of all-ceramics restorations for the sole use of particular patients. It is recommended for: single-tooth and bridgework restorations like crowns and bridges with one or two pontics, which can be used in the anterior as well as in the posterior tooth region.

Comparison of Technological Characteristics

Device name	Material Composition	Further Processing	Types	Physical Properties
DMC Nacera Pearl	Porcelain powder Y-TZP	Milling in CAM milling centers using CAD/CAM technique	pre-sintered blanks	ISO 13356 and ISO 6872
DMC Nacera Z / Z Medium	Porcelain powder Y-TZP	Milling in CAM milling centers using CAD/CAM technique	pre-sintered milling blank	ISO 13356 and ISO 6872
H.C. Starck StarCeram ® Z-Med	Porcelain powder	Milling in CAM milling centers using CAD/CAM technique	pre-sintered milling blank	ISO 13356 and ISO 6872
BEGO BeCe CAD Zirkon HT+	Porcelain powder	Milling in CAM milling centers using CAD/CAM technique	pre-sintered milling blank	ISO 13356 and ISO 6872
Wieland ZENO Zr	Porcelain powder	Milling in CAM milling centers using CAD/CAM technique	partially (pre-) sintered blank	ISO 13356 and ISO 6872

The main differences between the subject device and the noted predicates are based on slight variations in shade (the end sintered dental restorations shade differences are caused by the chemical composition differing mass fractions of the ‚oxide' components) as well as physical properties such as density and flexural strength.

Performance Testing

In order to demonstrate comparability of **Nacera Pearl** dental materials to the predicate devices a series of testing was performed according to ISO 13365 – in particular density, microstructure, flexural strength, and radio activity. Thermal expansion and chemical solubility was also performed according to ISO 13356. Open porosity, tensile strength, elastic limit, bending strength, Young's modulus comparative testing was also performed.

	The results of this testing showed that the physical properties and performance of the subject device are comparable to the identified predicates.
SE Conclusion:	In conclusion, it has been shown that all devices are dental materials manufactured from the same porcelain powder Y-TZP, have comparable indications for use, technical, physical, chemical, and biological properties and characteristics, and have the same aesthetic and diagnostic function. Therefore, it can be demonstrated that **Nacera Pearl** dental materials are substantially equivalent to the predicate dental devices, Nacera Z, Nacera Z Medium, BeCe CAD Zirkon HT+, StarCeram Z-Med, and ZENO Zr.