



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,

 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

## 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  (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_ (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**  
2015.06.25 12:39:57 -04'00'

### DOCERAM Medical Ceramics GmbH

Phone: +49 (0) 231 / 92 56 68 - 0  
Fax: +49 (0) 231 / 92 56 68 - 60  
info@doceram-medical.com  
www.doceram-medical.com

Hesslingsweg 65 - 67  
D - 44309 Dortmund  
Germany

Commerzbank Dortmund  
BLZ 440 400 37 · KTO 28 27 020  
BIC Code: COBADEFF440  
IBAN: DE92440400370282702000

Qualitätsmanagementsystem  
Certified Company  
DIN EN ISO 13485  
für Medizinprodukte