K041645 JUL - 9 2004

XI. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. October 8, 1998. [Separate Pages]

Submitter: Chris Scharf, DDS Services, 7375 S. Peoria, #105, Englewood, CO 80112

I. Classification names and numbers: Porcelain powder for clinical use, 76EIH, Class II.

II. Common/Usual name: Dental restorative material, porcelain powder/blocks

III. Proprietary name: DDS-ZR

IV. Establishment registration number: In process

V. Classification: These are class II devices, material restoratives, for the purpose of computer machining dental restorations (Crowns, Bridges, Inlays, and Onlays) per CFR 872.6660

VI. Device description: DDS-ZR is a Zirconia hybrid ceramic ideally suited for computerized dental machining applications. The dental professional prepares the appropriate tooth surfaces, sends a traditionally prepared impression to the lab where it is digitally reproduced, computer machined, and then returned to the dentist for placement. The dentists practice traditional luting/cementing techniques to permanently place the inlay or onlay. DDS-ZR is an alternative to gold, amalgam, porcelain, or composite filling materials, except that its application more closely resembles gold inlays or porcelain inlays or veneers in that they are actually prepared in a dental laboratory. The material is radio-opaque, for ready visualization.

VII. Substantial equivalence: Similar to devices currently on the market approved through the 510K process. DDS-ZR is similar to Cercon K-013230, Cynovad Zirkon K023327, and Denzir K984201.

The 510K "Substantial equivalence" decision-making process (detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to be luted/cemented permanently into place as inlays, and Onlays.

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market except for differences in methods of use. The technological features, although distinct, have the same intended use as the devices listed as equivalent.

3. Descriptive information provided shows that the material from which DDS-ZR are made are well established as the basis of many different kinds of hip implants, requiring significantly greater forces than in the mouth.

4. Zirconia has been repeatedly tested throughout the medical and dental industry and research has shown Zirconia to be highly biocompatible. The luting/cementing materials discussed in this summary are traditional materials well known to the dental industry.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2004

Charles Scharf
C/O Mr. Chris Scharf
FDA Correspondent
DDS Services, Incorporated
7375 South Peoria, #105 B-10
Englewood, Colorado 80112

Re: K041645
Trade/Device Name: DDS-ZR
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 10, 2004
Received: June 17, 2004

Dear Mr. Scharf:

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.

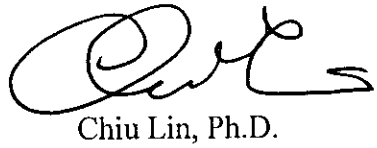
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K041645

510(k) Number (if known):_____

Device Name: **DDS-ZR**
Indications for Use:

Intended to restore carious lesions or structural defects in teeth. It is intended for use in cavities Classes I, II, V (Inlays and Onlays) and as a restorative material intended for veneers, crowns, and bridges

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K041645