K023327

DEC 0 2 2002

XI. 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS. [Separate Pages]

Submitter: Naoum Araj, Cynovad, 9710 Route Transcanadienne, St. Laurent (Quebec) CANADA H4S1V9.

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 Names: Cynovad Zirkon™

IV. Establishment Registration Number: Foreign, in process

V. Classification: These are Class II devices, used in prosthetic dentistry to produce a hard prosthesis with a glass-like finish and are described in CFR 872.6660.

VI. Device Description: Cynovad Zirkon™ is a zirconium dioxide-yttrium oxide ceramic, capable of machining by modern methods. The dentist prepares the tooth surfaces, sends a properly prepared impression of those surfaces to the dental laboratory where it is scanned and an inlay or onlay prepared by modern computerized lathe methods and returned to the dentist. The dentist then finally prepares the tooth surfaces involved and cements (lutes) the inlay or onlay in place with standard dental adhesives (luting) materials. Cynovad Zirkon™ inlays are alternatives to gold, amalgam, ceramic, porcelain, or composite filling materials, except that their application more closely resembles gold inlays or porcelain inlays, onlays or veneers in that they are actually prepared in a dental laboratory. The material is radio-opaque, for ready visualization.

VII. Substantial Equivalence: Relative to devices currently on the market, cleared by the 510(k) process, Cynovad Zirkon™ is basically identical with, Denzir™ cleared under K984201 and Cercon Base cleared under K-013230, and very similar to "Zirconium Oxide for the DCS Precident CAD/CAM System" cleared in K-001875. It is also equivalent to the older "Vita Cerec Blocks" cleared under K895901. It is similar to "Dicor Ceramic Inlay," cleared by Dentsply, Intl. under K884166.

The "510(k) "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 cemented/luted into place as inlays onlays, veneers or crowns, for the repair of damaged teeth.

2. The technological characteristics for this product are similar to those for the predicate device

and those currently on the market except for slight differences in methods of use.
In addition, the technological differences are well understood in the dental industry. The use of a computerized lathe system to prepare the inlay or only, when used in the dental office, also has been cleared by 510(k)–K950299 and K972276.

3. Descriptive information provided shows that the materials from which this device is made are well established in the more demanding areas of hip implants. They resemble the properties of finished porcelain products and usually will have porcelain finishes.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment III.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

CYNOVAD
C/O Dr. Neal Dunning
8309 Bryant Drive
Bethesda, Maryland 20817

Re: K023327
Trade/Device Name: Cynovad Zirkon™
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 25, 2002
Received: October 04, 2002

Dear Dr. Dunning,

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VIII.1 Indications for Use: [Separate Page]

510(k) Number: K023327

Device Name: Cynovad Zirkon™

Indications for use:

Intended for preparation of crowns, facings, veneers, inlays and onlays--to produce a hard prosthesis with a porcelain-like finish.

For fabricating copings and frameworks for inlays, onlays, veneers, crowns, anterior and posterior bridge restorations.

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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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