JAN 1 8 2005 K043472

XI. 510 (k) SUMMARY

Submitter: Dr. Abdeslam Kasseh, Vice President, MEDIN TECH, 6644 Abrams, St-Laurent (PQ). H4s 1Y1, (Quebec) CANADA.

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: Medin Tech Zirconia CP10, SS1000™

IV. Establishment Registration Number: Foreign, in process

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

VI. Device Description: Medin Tech Zirconia™ is a zirconium dioxide-yttrium oxide ceramic, capable of machining by modern CAD/CAM 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. Medin Tech Zirconia™ prostheses 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: Medin Tech Zirconia™, when it reaches the dentist, like porcelain "powder" prepared by the laboratory into an inlay or onlay, or as a bridge or crown, is a finished device ready for installation.

Relative to devices currently on the market, cleared by the 510(k) process Medin Tech is substantially equivalent to (virtually identical) to Cynovad Zirkon cleared in K023327 and equivalent to Denzir™ (Dentronic AB) cleared under K984201 as well as Cercon Base™ (Degussa Dental) cleared under K-013230. Like Cercon Base, it is intended to be marketed as a partially sintered device which will then be machined and fully sintered, but will also be available in an unsintered form. Like Austenal's DC Zirkon (001815) it can be used in the DCS CAD/CAM system, and in the CNC milling machine, or other CAD/CAM system meeting the requirements of the recently issued FDA Class II Special Controls Guidance for Optical Impression System...for Dental Restorations.

Medin Tech is also equivalent to the older "Vita Cerec Blocks" cleared under K895901. It is similar in use to "Dicor Ceramic Inlay," cleared by Dentsply, Intl. under K884166 (code ELW), to "Finesse All-Ceramic System" cleared by Dentsply, Intl., in K971869 (code EIH) and "Dental

Ceramic for Fabrication (K830955). These products, when they reach the dentist, are finished devices indicated for dental restorations, for inlays, onlays, veneers, and crowns for properly selected teeth.

We believe that the frequent prior use of the components of Medin Tech™ product in legally marketed devices, the similarity of the formulations used in this device and earlier devices, and the substantially equivalence of Medin Tech to prior cleared devices support the safety and effectiveness of the Medin Tech product for the intended use.

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 c crowns, for the repair of damaged teeth.

2. The technological characteristics for this product are similar to those for the predicate devices and thos currently on the market except for slight differences in methods of use. In addition, the technologica differences are well understood in the dental industry. The use of a computerized lathe system to prepare th inlay or only, when used in the dental office, also has been cleared by 510(k)--K950299 and K972276 an has been recognized in the recent FDA guidance on CAD/CAM systems.

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 and that they have been more recently recognized by their broad use in dental prosthesis. They resemble the properties of finished porcelain products and often will have porcelain finishes.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix V.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2005

Dr. Abdeslam Kasseh
Vice President
Medin Tech
6644 Abrams
St. Laurent (PQ) H4S 1Y1, Quebec
CANADA

Re: K043472
Trade/Device Names: Medin Tech Zirconia CP10™ and SS1000™
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 10, 2004
Received: December 16, 2004

Dear Dr. Kasseh:

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 (240) 276-0115. 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 S. Lin, PhD
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: ~~NA~~ K043472

Device Name: Medin Tech Zirconia CP10, SS1000™

Indications for use:

For fabricating copings and frameworks for inlays, onlays, veneers, crowns, anterior and posterior bridge restorations. The suitability of high purity dense yttria tetragonal zirconium oxide has been well demonstrated for surgical implant and more recently for many uses in the dental industry.

Intended for preparation of crowns, facings, inlays and onlays--to produce a hard prosthesis with a porcelain-like finish. Frequently will be used with porcelain overlay for translucence and related effects.

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__X___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control. Dental Devices
510(k) Number: K043472