K062695

XI. 510 (k) SUMMARY OCT 2 0 2006

Submitter: Larry Dang, Sagemax Bioceramics, Inc. 11061 NE 2nd St., Bellvue, WA 98004.

I. Classification Names and numbers: Porcelain powder for clinical use, EIH, Class II, described in CFR 872.6660.

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

III. Proprietary Names: Sagemax Z-Blank™

IV. Establishment Registration Number: In process

V. Device Description: Sagemax Z-Blank™ 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 prepares the final tooth surfaces involved and cements (lutes) the inlay or onlay in place with standard dental adhesives (luting) materials. Sagemax Z-Blank™ prostheses are alternatives to gold, amalgam, ceramic, porcelain, or composite filling materials, more closely resembling 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.

VI. Substantial Equivalence: Sagemax Z-Blank™ (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, Sagemax Z-Blank is substantially equivalent to Xavex cleared in K050903, to Medin Tech Zirconia CP10, 1000™ cleared in K043472, and 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. 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.

The successful prior use of the components of Sagemax Z-Blank™ product in legally marketed devices, the similarity of the formulations used in this device and earlier devices, and the substantially equivalence of Sagemax Z-Blank to prior cleared devices support the safety and effectiveness of the Sagemax Z-Blank™ 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 or crowns and for bridge components the repair of damaged teeth.
2. The technological characteristics for this product are similar to those for the predicate devices 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 and others.
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 V.

[End of Summary]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Larry Dang
President
Sagemax Bioceramics, Incorporated
11061 NE 2nd Street, Suite 168
Bellevue, Washington 98004

OCT 20 2006

Re: K062695
Trade/Device Name: Sagemax Z-Blank™
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 29, 2006
Received: September 11, 2006

Dear Mr. Dang:

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" (21 CFR 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/industry/support/index.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. Indications for Use: [Separate Page] K062695

510(k) Number: NA

Device Name: Sagemax Z-Blank™

Indications for use:

Intended for use in preparation of crowns, facings, inlays and onlays--to produce a hard prosthesis with a porcelain-like finish. Frequently used with porcelain overlay for translucence and related effects. 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 many uses in the dental industry

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.

Prescription Use __X__ (Per 21 CFR 801.Subpart D ) OR Over-The-Counter Use_____ (Per 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)

Ron Mabley for MSK

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

510(k) Number: K062695