K090976

VII. Section 10 – 510(K) Summary

This summary of 510(K) substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92

1. **Applicant's Name and Address**

Whip Mix Corporation,
Lab Services Division
361 Farmington Ave.
Louisville, Kentucky 40217
Telephone Number: 502-634-1451
Fax Number: 502-634-4512
Contact Person: Frederick T. Kapp
Quality Manager

JUN 25 2009

2. **Name of Device**

Trade Name:	Vericore™ Abutment
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment 21 CFR 872.360
Product code:	NHA

3. **Legally Marketed Device to which Equivalence is claimed(Predicate Device)** Vericore Zirconia Abutments for Replace K082299 Atlantis Zirconia Abutments K071946, K052070, K062277

4. **Description of Device**

The Devices covered in this submission are abutments which are placed on the dental implant to provide support for a prosthetic restoration.

Vericore Abutments are made from biocompatible yttria-stablized zirconia blocks. The abutment screws are made from Titanium grade Ti-6A1-4V The abutment is placed over the implant and is mounted on to the implant with an abutment screw The abutments are compatible with the following implant systems:

Zimmer – Narrow, Regular, Wide
Nobel Biocare – Narrow, Regular, Wide
3i –Micro Mini, Regular Hexed, 5mm
3i Certain – Narrow, Regular, Wide
Southern Hexed – Narrow, Regular, Wide
Endopore – Narrow, Regular and 5mm
Astra – Narrow and Regular
Straumann - Narrow, Regular, Wide

5. **Intended use of the Device**

The intended uses of the devices covered by this submission are abutments which are placed on the dental implant to provide support for a prosthetic reconstruction. The Vericore abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support a single and multiple tooth prosthesis, in the mandible or maxilla. The abutment screw is intended to secure the abutment to the endosseous implant.

6. **Basis for Substantial Equivalence**

Vericore abutments are substantially equivalent to Atlantis Zirconia Abutments (K052070 and K063734). Both devices are Zirconia abutments designed to fit the Nobel Biocare, 3i, Zimmer, and Endopore implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2009

Whip-Mix Corporation
C/O Ms. Angela Blackwell
Consultant
The Biologics Consulting Group
361 Farmington Avenue
Louisville, Kentucky 40217

Re: K090976
Trade/Device Name: Vericore™ Abutment in Zirconia for Implant Systems, See List Below
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 3, 2009
Received: April 6, 2009

Dear Ms. Blackwell:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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

510(k) Number:
Device Name: Vericore™ Abutment in Zirconia for Implant Systems, See list below.

The Vericore Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely endentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The abutment is placed over the implant and is mounted on to the implant with an abutment screw.

This device is compatible with the following manufacturers' implant systems: Branemark, Southern Hexed, 3i, 3i Certain, Zimmer and Endopore.

This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional.
Also highly angled abutments (i.e. 15 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.

Zimmer – Narrow, Regular, Wide
Nobel Biocare – Narrow, Regular, Wide
3i –Micro Mini, Regular Hexed, 5mm
3i Certain – Narrow, Regular, Wide
Southern Hexed – Narrow, Regular, Wide
Endopore – Narrow, Regular and 5mm
Astra – Narrow and Regular
Straumann - Narrow, Regular, Wide

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Dr Robert S Betz DDS for Dr. Kevin Mulvey
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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