K130991

FEB 10 2014

SECTION 4: 510(k) SUMMARY

I. **Submitter Information:** SAGEMAX BIOCERMAICS, INC., 34210 9th Avenue South, Suite 118, Federal Way, WA 98003 USA **Contact Person:** Katie J. Kosty – Phone: 877-386-0389, Fax: 888-856-2615

Date Prepared: November 26, 2013

II. **Classification**: Porcelain powder for clinical use, EIH, Class II, described in CFR 872.6660.

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

IV. **Proprietary Names**: NexxZr™ S and NexxZr™ T (formerly Sagemax Z-Blank™)

V. **Establishment Registration Number**: 3007518500

VI. **Indications for Use:** NexxZr™ are intended for the fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.

VII. **Device Description**: Sagemax NexxZr™ T and NexxZr™ S are zirconium dioxide-yttrium oxide ceramic material – pressed into pre-sintered discs intended for further processing using computer aided manufacturing by a dental laboratory or other similar establishment, under the order of a physician/dentist. The dentist prepares the surface(s) of the natural teeth, then cements (lutes) the restoration in place with standard dental adhesives materials. Sagemax NexxZr™ prostheses are alternatives to gold, amalgam, ceramic, porcelain, or composite filling materials, more closely resembling gold inlays or porcelain inlays, onlays or veneers. The material is radio-opaque, for ready visualization.

NexxZr™ products are a modification of the previous version, Sagemax Z-Blank™.

VIII. **Substantial Equivalence:** Sagemax NexxZr™ materials are substantially equivalent to our current, legally marketed device, K062695, Sagemax Z-Blanks; they are intended for the same purpose, namely to fabricate crowns (temporary or permanent) that are fully anatomical and contoured mimicking natural teeth. Yttrium-stabilized zirconia has been studied extensively for use in medical applications. The material is inert (biocompatible) and ideal for long-term implantable devices that resist failure under extreme load and stress. There are numerous dental devices that have been cleared by the Agency that apply the same fundamental scientific technology with regard to design and process. These devices have shown to be substantially equivalent in safety and/or effectiveness to the predicate device. Therefore, NexxZr™ S and NexxZr™ T are substantially equivalent to the following predicate device:

K062695 – Sagemax Bioceramics – Sagemax Z-Blank

Description of Safety and Substantial Equivalence:

Technological Characteristics

NexxZr™ is an oxide-based ceramic composed of isostatically pressed, partially sintered, yttria-stabilized zirconia powder. NexxZr™ is tested according to ISO 6872: 2008 Type II/Class 6 to ensure intended strength. This material is similar to dental alloys containing gold. Predicate devices have been used extensively and were found to be safe for dental use. The devise has the same technological characteristics and composition as the predicate device Sagemax Z-blank™.

Non-Clinical Performance Data

Measurements of the physical characteristics showed that the material has the same mechanical (flexural strength) and chemical stability (solubility) as our predicate device.

Conclusion as to Substantial Equivalence

The physio-chemical properties of the raw material used in Sagemax devices, in addition to its technological characteristics are the same as in our previously cleared predicate device. The substantial equivalence of the intended use has also been proven by material testing (flexural strength – ISO 6872: 2008) and clinical performance.

The devices are meant to be used in the same manner as current, legally marked devices. They are intended to be used in conjunction with CAD/CAM systems that meet the requirements under the recently issued FDA Class II Special Controls Guidance for Optical Impression Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2014

Sagemax Bioceramics, Inc.
Ms. Kathryn J. Kosty
Vice President
34210 9th Avenue South, Suite 118
Federal Way, WA 98003

Re: K130991
Trade/Device Name: NexxZr® T and NexxZr® S
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 2, 2013
Received: December 5, 2013

Dear Ms. Kosty:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130991

Device Name
NexxZr S and NexxZr T

Indications for Use *(Describe)*
NexxZr T and NexxZr S are intended for the fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Susan Runner -S
Mary S. Runner -S
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