K103494

FEB 16 2011

5. 510 (k) Summary

This 510(k) summary provides the basic principle for determination of substantial equivalence according to 21 CFR Part 807.92.

1. Submitter of 510(k)

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2. Device name

Trade name:	ZENOSTAR Magic Glaze
Common name:	Ceramic Spray Glaze
Classification name:	Powder, Porcelain (21 CFR 872.6660, Product code: EIH, Class II)

3. Legally marketed equivalent device

Predicate device:	Nova Ceramic Spray Glaze and Tru- Paque , Opaque Porcelain
510(k) number:	K030859

Date of Summary: 11/02/2010

4. Description of the Device

ZENOSTAR Magic Glaze is dental porcelain, which is made of glass frit and is applied in an aerosolized form. It can be used by professional dental technicians to glaze dental porcelain –fused-to-metal as well as all-ceramic restorations, like milled zirconium dioxide crowns and bridges.

This application method decreases the production time compared to the conventional build-up methods, where glaze ceramic powder has to be mixed with suitable liquids and layered onto the restoration with a brush.
After spraying on, ZENOSTAR Magic Glaze has to be fired at about 900°C for 1-2 minutes in a ceramic furnace to achieve its final properties.

Generally, the glaze bake determines the surface finish of the ceramic veneer and thereby significantly affect the esthetical appearance of the restoration.
ZENOSTAR Magic Glace allows spraying on even and very thin layers of glace material, thus providing the possibility to control shining and optical reflection of the restoration by repeating the procedure.

It can be applied on single unit or multiple unit restoration at one time, and, in addition, it can be sprayed over unfired ceramic stains and body-stains, which are often used to match the color of the patient's natural teeth. These possibilities save time of additional firing cycles and enhance the efficiency of the application of ZENOSTAR MAGIC Glaze.

5. Intended Use of the Device

ZENOSTAR Magic Glaze is intended to be used by dental technicians for glazing dental restorations like crowns and bridges. Although primary intended to be used for milled zirconium dioxide restorations, it can also be applied to porcelain-fused-to-metal and to veneered all-ceramic restorations, if their veneering ceramics are suitable with respect to their CTE, e.g. Reflex ceramic or Zirox ceramic of Wieland Dental + Technik.

6. Comparison with the predicate device

ZENOSTAR Magic Glaze is substantially equivalent to the medical device Nova Ceramic Spray Glaze.
ZENOSTAR Magic Glaze as well as "Nova Ceramic Spray Glaze" is dental porcelain, which is made of glass frit and has to be applied in aerosolized form. Both have similar indications for use, in which they are intended to be used by professional dental technicians to glaze dental restorations, like crowns and bridges.
Physical, biological and chemical properties of the device, like bending strength, coefficient of thermal expansion, biocompatibility, and chemical solubility were tested according to international accepted standards, e.g. ISO 6872, ISO 7405, and meet their demands, respectively, and indicate high safety and effectiveness.
Considering these excellent material properties and the numerous similarities as well as the lack of any significant differences between both devices, it can be concluded, that ZENOSTAR Magic Glaze is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Wieland Dental + Technik GmbH & Co. KG
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GERMANY

FEB 16 2011

Re: K103494
Trade/Device Name: ZENOSTAR Magic Glaze
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 23, 2010
Received: November 29, 2010

Dear Dr. Polzer:

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 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/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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

21.8. Indication for use statement

Indications for Use

510(k) Number (if known): K103494

Device Name: ZENOSTAR Magic Glaze

Indications for Use:

The spray glaze ZENOSTAR Magic Glaze is a ready to use and easy to apply, spray on ceramic glaze, which is primarily intended for ZENOSTAR Zr restorations, manufactured with the help of the ZENOTEC Systems. However, veneered zirconium oxide restorations, (ZIROX and ZENOFLEX dimension) and metal ceramic restorations (REFLEX and REFLEX dimension) can also be glazed with the spray glaze ZENOSTAR Magic Glaze. ZENOSTAR Magic Glaze spray glaze can be used together with and/or at the same time as the relevant specific ceramic stains.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K103494

(Posted November 13, 2003)