FDA CDRH DMC

OCT 15 2010

Received

K102351

510(k) SUMMARY

Contact: M. Th. Plaumann

Date prepared: August 16, 2010 NOV - 2 2010

Trade or proprietary name: **Grandio SO**

Classification name: Material, Tooth Shade, Resin (872.3690)

Predicate device: Grandio, K051867, VOCO GmbH

Device description:

Grandio SO is a condensable, methacrylate based dental filling composite for all cavity classes with high inorganic filler content. The material features excellent physical properties e.g. wear resistance, compressive strength, color stability and durability in the mouth. **Grandio SO** comes in different tooth like shades of optimal opacity and can be easily polished. It is therefore highly qualified for long lasting, esthetic restorations.

Grandio SO is processed according to current state of the art procedures for light curing condensable dental composites, thus, **Grandio SO** can be applied by any dental professional who is familiar with this kind of materials. Like the predicate device Grandio it can easily be contoured and shaped prior to curing and finishing.

Intended use:

Grandio SO is intended for use as:

- class I to V fillings
- reconstruction of traumatically affected anteriors
- facetting of discolored anteriors
- correction of shape and shade for improved aesthetic appearance
- locking, splinting of loose anteriors
- repairing veneers
- restoration of deciduous teeth
- core-build-up under crowns
- composite inlays

Technological characteristics:

Grandio SO and the legally marketed device **Grandio,** K051867 (**VOCO GmbH**) share the same indications but have improved physical features. **Grandio SO** has been optimized with regard to several physical parameters.

Grandio SO based on nanohybrid technology just like the predicate device **Grandio**. This technology relies on the optimal mixture of inorganic filler diameters.

The components of **Grandio SO** serve the same purpose as the ingredients of the predicate device Grandio.

The prior use of all of the components of **Grandio SO** in legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.

We believe that the prior use of the components of **Grandio SO** in legally marketed devices and the performance data and results also provided support the safety and effectiveness of **Grandio SO** for the intended use.

VOCO GmbH, October 13th, 2010

Dr. Thorsten Gerkensmeier
(Regulatory Affairs)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Manfred T. Plaumann
Managing Board
Voco GMBH
Anton-Flettner-Strasse 1-3
Cuxhaven Germany D-27472

NOV - 2 2010

Re: K102351
Trade/Device Name: Grandio SO
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: October 13, 2010
Received: October 15, 2010

Dear Mr. Plaumann:

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.

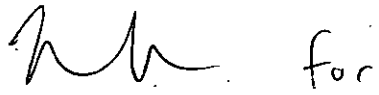
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Indications for Use Statement

510(k) Number: K102351

Device Name: ____ **Grandio SO** ____

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Indications for Use:

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- restoration of deciduous teeth
- core-build-up under crowns
- composite inlays

Prescription Use __X___ OR **Over-The-Counter Use** _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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