K102354

510(k) SUMMARY

Contact:	M. Th. Plaumann
Date prepared:	August 16, 2010
Trade or proprietary name:	**Grandio SO Heavy Flow**
Classification name:	Material, Tooth Shade, Resin (872.3690)
Predicate device:	Grandio Flow, K051868, VOCO GmbH Grandio Flow, K101213, VOCO GmbH

NOV - 8 2010

Device description:

Grandio SO Heavy Flow is a steady but shear thinning, methacrylate based dental filling composite for all cavity classes with increased inorganic filler content and excellent physical properties e.g. wear resistance, compressive strength, color stability and durability in the mouth compared with other flow composites. **Grandio SO Heavy Flow** 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 Heavy Flow is processed according to current state of the art procedures for light curing flowable dental composites, thus, **Grandio SO Heavy Flow** can be applied by any dental professional who is familiar with this kind of materials. Like the predicate device Grandio Flow it can easily be placed and processed prior to curing and finishing.

Intended use:

Grandio SO Heavy Flow is intended for use as:
- filling minimally invasive cavities of all classes
- filling small class I cavities and extended fissure sealing
- filling class II – V cavities including V-shaped defects and cervical caries
- blocking out undercuts
- lining or coating cavities
- repairing fillings and veneers
- luting translucent prosthetic pieces (e.g., full ceramic crowns, etc.)

Technological characteristics:

Grandio SO Heavy Flow and the legally marketed device **Grandio Flow,** K051868 (**VOCO GmbH**) share the same indications but have improved physical features. **Grandio SO Heavy Flow** has been optimized with regard to several physical parameters.

Grandio SO Heavy Flow based on nanohybrid technology just like the predicate device **Grandio Flow**. This technology relies on the optimization of the mixing ratio of inorganic filler particles in different sizes.

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

The prior use of all of the components of **Grandio SO Heavy Flow** 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 Heavy Flow** in legally marketed devices and the performance data and results also provide support for the safety and effectiveness of **Grandio SO Heavy Flow** for the intended use.

VOCO GmbH, September 6th, 2010

Dr. Thorsten Gerkensmeier
(Regulatory Affairs)

Device Description and Executive Summary

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

Grandio SO Heavy Flow will be offered in the following presentations:

- syringes of 2g
- Caps of 0.25g

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Grandio SO Heavy Flow is claimed to be substantially equivalent to **Grandio Flow**, K051868, K101213 (VOCO GmbH)

For details of product performance data please see section 9 (substantial equivalence comparison).

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
Voco GmbH
Anton-Flettner-Strasse 1-3
Cuxhaven
Germany D-27472

NOV - 8 2010

Re: K102354
Trade/Device Name: Grandio SO Heavy Flow
Regulation Number: 21 CFR 872.3690
Regulatory Class: II
Product Code: EBF
Dated: October 13, 2010
Received: October 15, 2010

Dear Mr. Plaumann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (240) 276-6649. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

NOV - 8 2010

Indications for Use Statement

510(k) Number: K102354

Device Name: ____ **Grandio SO Heavy Flow** ____

Indications for Use:

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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)

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

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