K090817

510(k) SUMMARY

JUL 28 2009

Contact: Manfred Th. Plaumann

Date prepared: March 24th, 2009

Trade or proprietary name: **Ionolux**

Classification name: Cement, Dental (872.3275)

Predicate device: GC Fuji II LC improved (K961584, GC America, Inc.)

Device description: **Ionolux** is a resin-reinforced radiopaque light-curing glass-polyalkenoate restorative. The material has outstanding aesthetics, good handling properties and high chemical adhesion.

Intended use:

Ionolux is intended for the following applications:

- 1. Restorations class III and V, especially cervical fillings and root caries
- 2. Fillings on deciduous teeth
- 3. Small class I fillings
- 4. Temporary fillings
- 5. Core build-up
- 6. Lining

Technological characteristics: All of the components of **Ionolux** are found in the legally marketed device GC Fuji II LC improved (K961584, GC America, Inc.)

The prior use of all of the components of **Ionolux** 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 **Ionolux** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **Ionolux** for the intended use.

VOCO GmbH, March 24th, 2009

Manfred Th. Plaumann
Managing Board

VOCO GMBH
Anton-Flettner-Str. 1-3
27472 CUXHAVEN
Germany

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. M. Th. Plaumann
VOCO GmbH
Anton- Flettner- Strasse 1-3
Cuxhaven
Germany D-27472

JUL 23 2009

Re: K090817
Trade/Device Name: IONOLUX
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: July 9, 2009
Received: July 14, 2009

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.

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 Statement

510(k) Number: K090817

Device Name: **Ionolux**

Indications for Use:

Ionolux is intended for the following applications:

- 1. Restorations class III and V, especially cervical fillings and root caries
- 2. Fillings on deciduous teeth
- 3. Small class I fillings
- 4. Temporary fillings
- 5. Core build-up
- 6. Lining

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)

Kevin M. Ely for MSR

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

510(k) Number: K090817