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Ihr Zeichen yr ref.	Ihre Nachricht vom dtd.	Unser Zeichen our ref.	Datum date

510(k) SUMMARY

Contact: Dr. Süs

Date prepared: November 29, 2005

Trade or proprietary name: **x-tra fil**

Classification name: Tooth shade resin material (872.3690)

Predicate device: Quixx Posterior Restorative K 040144

Device description: **x-tra fil** is a hybrid resin composite restorative material for use in filling posterior dental cavities. The restorative consists of a single paste that is visible/blue light cured.

Intended use: **x-tra fil** is indicated for posterior Class I and Class II cavities and core build-up.

Technological characteristics: All of the components of **x-tra fil** are found in the legally marketed devices K 040144, K 994056, K 926458, K 040769, K 030914, K 912425.

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

VOCO GmbH, November 29, 2005

Dr. Michael Süs
Mgr. for regulatory affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2006

Dr. Michael Sus
Manager
Voco GmbH
Anton-Flettner-Strasse 1-3
Cuxhaven, Germany D-27472

Re: K053391
Trade/Device Name: x-tra fil is Intended for light curing Class I and class II Posterior Fillings and Core Build-up
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: November 29, 2005
Received: December 7, 2005

Dear Dr. Sus:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu Lin, Ph.D.
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: K053391

Device Name: **x-tra fil**

Indications for Use:

x-tra fil is intended for light curing class I and class II posterior fillings and core build-up.

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
510(k) Number 2/15/06