Schütz-Dental GmbH • Dieselstraße 5-6
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Geschäftsführer:
Horst Schütz • Wolf Zientz

Amtsgericht
Friedberg HRB 156

K 052189

Premarket Notification 510(k)

OCT 17 2005

SCHÜTZ DENTAL GROUP

510(k) Summary

Submitter of 510(k):	Schütz-Dental GmbH Dieselstr. 5-6 61191 Rosbach Germany Phone: +49/60 03/8 14-0
Contact person:	Mr. Michael Wierz Phone: +49/60 03/8 14-367 Fax: +49/60 03/8 14-906 email: m.wierz@schuetz-dental.de
Date of Summary:	2005-08-09
Name of device:	ReVeneer Ceramic Repair System with the following components: 1. Primer 2. Base 3. Opaquer (light and dark) 4. Composite Fillis
Classification name:	1. Agent, Tooth Bonding, Resin 2. Agent, Tooth Bonding, Resin 3. Powder, Porcelain 4. Material, Tooth Shade, Resin
Product code:	1. KLE 2. KLE 3. EIH 4. EBF
C.F.R section:	1. (872.3200) 2. (872.3200) 3. (872.6660) 4. (872.3690)
Legally marketed equivalent devices:	1. Kuraray Alloy Primer (510(k) no.: K974089) 2. Kuraray Clearfil Photo Bond (510(k) no.: K943165) 3. Shofu Vintage Halo (510(k) no.: K973247) 4. Ultradent Amelogen Plus (510(k) no.: K043119)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2005

Mr. Michael Wierz
Export Sales Manager
Schütz Dental GmbH
Dieselstr. 5-6
Rosbach Hessen 61191
GERMANY

Re: K052189
Trade/Device Name: Reveneer Ceramic Repair System
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: August 9, 2005
Received: August 16, 2005

Dear Mr. Wierz:

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.

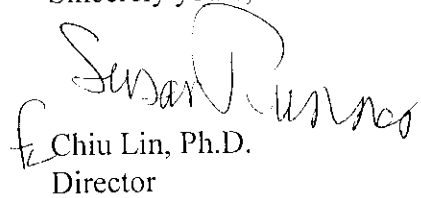
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K052189
Device Name: ReVeneer Ceramic Repair System
Indications for Use:

ReVeneer is an intraoral and extraoral repair system for ceramic crown and bridge veneers with the following advantages:

- no acid etching (neither hydrofluoric nor phosphoric acid)
- safe intraoral use
- extremely good bond strength
- time saving
- can be used universally, with all conventional ceramics
- use of conventional curing lights (halogen, LED, plasma)

Prescription Use ✓ (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)

Susan Runner

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

510(k) Number: K052189