WIELAND
Dental + Technik

Wieland Dental + Technik
GmbH & Co. KG
Schwenninger Straße 13
D-75179 Pforzheim
Postfach 24 40
D-75014 Pforzheim

K050203

5. 510 (k) Summary

FEB 14 2005

Submitter of 510(k):	**Wieland Dental + Technik GmbH & Co. KG** **Schwenninger Str. 13** **D-75179 Pforzheim** **Germany** **Phone: +49-7231-3705-0**
Contact person: Phone: Fax: e-mail:	**Dr. Gerhard Polzer** **+49–7231–3705–219** **+49-7231-357959** **gerhard.polzer@wieland-dental.de**
Date of Summary:	**2005-01-20**
Trade name:	**Allux®**
Classification name: Product code: C.D.R section: Classification:	**Porcelain powder for clinical use** **EIH** **872.6660** **Class II**
Legally marketed equivalent device:	**Procera All-Ceramic Porcelain**
510(k) number:	**K944702**

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510 (k) Summary

Device description

Allux® is a dental porcelain system that consists of 127 different ceramic powders.

It is intended to be used by professional dental technicians to manufacture all-ceramic dental appliances for the sole use of particular patients.

Allux® is recommended for veneering alumina oxide (Al_2O_3) frameworks, in which it provides an easy to use dental restorative material to fabricate dental restorations with the best possible aesthetic results.

The coefficient of thermal expansion [CTE $_{(25\text{-}500°C)}$] of these alumina oxide (Al_2O_3) frameworks had to be approximately 8 x 10^{-6} K^{-1}.

Allux® meets all applicable requirements of the standard ISO 6872: 1995 "Dental ceramic".

Type of Powder	Shades
Liner	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4; White, Yellow, Violet, Orange, Brown, Gum
Dentine	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4; Crystal 1 light; Crystal 2 pearl; Crystal 3 creme; Gum 1; Gum 2; Gum 3; Gum 4, Gum 5
Chroma-Dentine Chromatix	A1; A2; A3; A3,5; A4; B1; B2; B3; B4; C1; C2; C3; C4; D2; D3; D4
Dentine Modifier	Mocca; Corn; Mango; Caramel; Khaki; Brown; Yellow; Ivory;
Flu-Dentines	Flamingo; Straw; Bright; Sunny; Crystal;
Incisal / Enamel	Incisal 1, Incisal 2, Incisal 3; Incisal 4; Topas; Anthrazit; Amethist; Aquamarin; Citrin; Rubin; Lemon; Melon; Transpa Neutral; Transpa Clear
Opale incisal	Opale Incisal 1, Opale Incisal 2, Opale Incisal 3, Opale Incisal 4, Crystal Blue, Frosty, Milky, Snow, Ice
Shoulder porcelains margin	High Flu, High 1, High 2, High 3, High 4, High Red, High Crystal; Low Flu, Low 1, Low 2, Low 3, Low 4, Low 5, Low Bleach
Stain	White; Black; Grey; Caramel; Orange; Ocker; Peach; Melon; Blue; Steel; Violet; Gum; Marone; Olive; Ivory; Yellow; Bodystain A; Bodystain B; Bodystain C; Bodystain D
Glaze	Glaze
Correction	Correction

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2005

Gerhard Polzer, Ph.D.
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

Re: K050203
Trade/Device Name: Allux®
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 20, 2005
Received: February 01, 2005

Dear Dr. Polzer:

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.

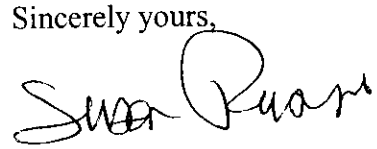
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K050203

DEVICE NAME: Allux®

INDICATIONS FOR USE:

Allux® is a dental silicate-glass ceramic that can be used by dental technicians to fabricate all-ceramic restorations by veneering aluminium oxide (Al_2O_3) frameworks.

The coefficient of thermal expansion [CTE (25 - 500°C)] of these aluminium oxide (Al_2O_3) frameworks had to equal approximately 8.0 x $10^{-6}K^{-1}$.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

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

510(k) Number: K050203