

K091826

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SEP 25 2009

Submitter

Company:.....3M ESPE AG
 Street:.....ESPE Platz
 ZIP-Code, City:.....D-82229 Seefeld
 Federal State:Bavaria
 Country:Germany
 Establishment Registration Number9611385
 Official Correspondent:Dr. Desi W. Soegiarto,
Regulatory Affairs Specialist
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 Date:.....June 05, 2009

Name of Device

Proprietary Name:.....Elegant
 Classification Name:.....Porcelain powder for clinical use
 Common Name:Glass ceramics, stains, shades, glaze,
 liquids

Predicate Device

Lava Ceram by 3M ESPE.....K011394 -
 IPS Empress Universal Shade/Stains.....Presumably K980986
 by Ivoclar Vivadent
 Glass Ceramics "Jolly" by 3M ESPEK053438
 Position Penta by 3M ESPE.....K974231
 Ketac Molar Quick by 3M ESPE.....K994251

Description for the Premarket Notification

Elegant is classified as Porcelain powder for clinical use (21 C.F.R. § 872.6660). Elegant is used for production of glass ceramic veneers for 3M ESPE Lava™ Frame Zirconia frameworks.

Elegant consists of 4 glass ceramic blocks (E1 – E4), from which the veneer is milled. Each ceramic block is available in the two sizes S and M. The veneer is then fused to the Zirconia framework via color-coordinated fusion porcelain (D1 – D10). For smaller adjustments to the restoration, corrective porcelains (CR1 – CR4) can be used. For the tooth colors A4, B4, C3, C4, and D4, the basic shades (“Shade” A – D) must be used. The individual stains S1 (White), S2 (Lemon Yellow), S3 (Orange), S4 (Violet), S5 (Blue), S6 (Dark Brown), and glaze are used for individualization. For the mixing of the fusion porcelain powder and the corrective porcelain, modelling liquid is available; also, for stains and glaze, stain/glaze liquid is available.

For the production of an Elegant restoration, the Lava™ Frame Zirconia framework and the corresponding Elegant veneer are virtually designed on the screen with the Lava™ Design Software. The milling for both parts takes place in the accordingly released Lava™ milling machine with special milling cutters. Subsequently the Lava™ Frame Zirconia framework is shaped and then sintered in the Lava™ sintering furnace. All of the above-mentioned Lava products are manufactured by or for 3M ESPE.

The comparison for chemistry, performance data and indications for use shows that Elegant is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for Elegant are completely met.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
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3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria
GERMANY D-82229

SEP 25 2009

Re: K091826
Trade/Device Name: Elegant
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 15, 2009
Received: September 18, 2009

Dear Dr. Soegiarto:

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.

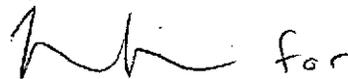
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 Division 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):

K091826

Device Name:

Elegant

Indications For Use:

CAD/CAM veneering for anterior and posterior single crowns made of Lava Frame Zirconia, manufactured with Lava Design Software and the accordingly released Lava milling machine.

Prescription Use X
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Muly for MR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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