K072055 1/2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M ESPE AG

Strect:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

Official Correspondent: .....Dr. Andreas Petermann,

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Date:.....July 23, 2007

Name of Device

Proprietary Name:.....Lava™ Frame, Lava™ Frame Shade

Classification Name:.....Porcelain powder for clinical use

.....Endosseous dental implant abutment

Common Name: .....All-ceramic core material

.....All-ceramic stain solution

.....Abutment

Predicate Device

ALTATEC Camlog Implant System and

Abutments by Altatec Biotechnologies K032448

1562

K072055

Description for the Premarket Notification

Lava™ abutment made from Lava™ Frame zirconia mill blanks and dyed with Lava™ Frame Shade is classified as endosseous dental implant abutment (21 C.F.R. § 872.3630) because it is a prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Lava™ Frame and Lava™ Frame Shade are parts of the Lava™ system (K011394). Lava™ Frame Zirconia mill blanks are used for the fabrication of frameworks for all-ceramic restorations. The frameworks for onlays, inlays, veneers, crowns and bridges are designed and manufactured by CAD/CAM technology, whereas the CAM fabricated Lava™ Abutments made from Lava™ Frame Zirconia mill blanks will be designed by means of a traditional wax up technique. The wax up will be scanned (Lava™ Scan, K062493) and milled without any further design step in the CNC milling unit Lava™ Form. After milling, the abutments are dyed with one of the 7 Lava™ Frame Shade dyeing liquids as required to achieve the desired tooth color, then sintered. The dyed abutments are sintered using the specialized program of the Lava™ Therm sintering furnace.

The wax up designed abutment will be cemented to a titanium interface which will be subsequently screwed into the respective implant (e.g. Camlog, Altatec Biotechnologies).

The comparison for composition, performance data and indications for use shows that Lava™ abutment made from Lava™ Frame and dyed with Lava™ Frame Shade is substantially equivalent to the predicate device.

In summary, it can be concluded that safety and effectiveness requirements for Lava™ Frame and Lava™ Frame Shade for the fabrication of abutments are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

MAR 29 2011

Re: K072055
Trade/Device Name: Lava™ Frame, Lava™ Frame Shade
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 18, 2008
Received: February 21, 2008

Dear Dr. Soegiarto:

This letter corrects our substantially equivalent letter of February 26, 2008.

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 (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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
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): K072055

Device Name: Lava™ Frame, Lava™ Frame Shade

Indications For Use: The Lava™ system is intended for CAD/CAM fabrication of all-ceramic dental restorations.

The system is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Lava™ Frame and Lava™ Frame Shade are intended for the manufacturing of abutments. The titanium connection for the abutment must meet the following dimensions:
- Overall cementation surface > 30 mm²
- Height of the head of the titanium interface from the shoulder > 2.8 mm

The following systems fulfill the above described specifications:
- Co. Alltec Dental GmbH: Camlog Titanium-base for Ceramic-abutment – Abutment ø ≥ 4.3 mm
- Co. Dentsply Friadent GmbH: Friadent Cera Base
- Co. Neoss GmbH: Neo Link Neoss Mono Abutment Titanium; Neo Link Neoss Multi Abutment Titanium; Neo Link Neoss Mono Aesthetic Abutment Titanium; Neo Link Neoss Multi Aesthetic Abutment Titanium; Matrix Abutment Hex – Regular Mono Titan; Matrix Abutment Hex – Regular Multi Titan; Matrix Abutment Hex – Narrow Mono Titan; Matrix Abutment Hex – Narrow Multi Titan; Matrix Abutment C-Lect – Regular Mono Titan; Matrix Abutment, C-Lect – Regular Multi Titan; Matrix Abutment C-Lect – Narrow Mono Titan; Matrix Abutment C-Lect – Narrow Mono Titan; Matrix Abutment ST – Mono Titan; Matrix Abutment ST – Mono Titan

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Susan Runner

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

510(k) Number: K072055