K062493

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 17 2006

Submitter

Company:	3M ESPE AG
Street:	ESPE Platz
ZIP-Code, City:	D-82229 Seefeld
Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
Official Correspondent:	Dr. Andreas Petermann, Manager Regulatory Affairs
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Date:	August 22, 2006

K062493

Name of Device

Proprietary Name:	Lava software
Classification Name	Porcelain powder for clinical use
Common Name:	All-ceramic core material All-ceramic overlay material

Predicate Device:

Procera® Software by Nobel Biocare USA LLC, K053602

Description for the Premarket Notification

The Lava™ software is used with 3M ESPE's Lava™ system, an all-ceramic system for the CAD/CAM fabrication of dental restorations such as inlays, onlays, veneers, crowns and bridges. The Lava software controls the measuring process, editing of the measurement data (CAD), and export of the data to the milling machine. A software module of the Lava satellite scanner facilitates the transfer of 3D data (plain scan data or fully modeled data) to the remote milling machine via internet by a secured internet connection.

In summary, Lava™ software as described in this 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Sabine Krisher
3M ESPE AG
ESPE Platz
D-82229 Seefeld
Bavaria
GERMANY

NOV 17 2006

Re: K062493
Trade/Device Name: Lava Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, EIH
Dated: August 22, 2006
Received: August 25, 2006

Dear Dr. Krischer:

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.

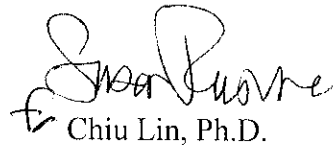
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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): K062493

Device Name: Lava software

Indications For Use: The Lava software is used with 3M ESPE's Lava system, an all-ceramic system for the CAD/CAM fabrication of dental restorations such as inlays, onlays, veneers, crowns and bridges.
The software controls the measuring process, processing of the measurement data (3D-CAD tool), and export of the data to the milling machine. In addition, various patient and case information elements can be entered. Other functions are available for verification and service of the measuring system.
The Lava software also facilitates the transfer of 3D data from a scanner to a remote milling machine via internet.

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number: K062493

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)