

K111257

MAY 13 2011

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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. Desi W. Soegiarto,  
.....Regulatory Affairs Specialist  
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Date:.....April 15, 2011

Name of Device

Proprietary Name:.....Heisenberg Dyeing Liquids  
Classification Name:.....Porcelain powder for clinical use  
Common Name: .....Dyeing liquid

Predicate Device

Lava Frame Shade by 3M ESPE, Germany.....K011394

### Description for the Premarket Notification

Heisenberg Dyeing Liquid is classified as Porcelain powder for clinical use (21 C.F.R. § 872.6660).

Heisenberg Dyeing Liquid is intended to be used for the shading of Heisenberg zirconia frameworks and Heisenberg all-zirconia, monolithic restorations for anterior and posterior teeth.

Heisenberg Dyeing Liquids will be available in various shades which are corresponding to every tooth color.

Predicate device to which Heisenberg Dyeing Liquids have been compared is Lava Frame Shade by 3M ESPE (K011394). Lava Frame Shade is suited to be used for the shading of zirconia frameworks and all-zirconia, monolithic restorations (made from Lava Mill Blanks by 3M ESPE, K011394) for anterior and posterior teeth. The difference to the predicate device is primary in the change of coloring ions and secondary in the change of the general chemistry.

In this 510(k) premarket notification Heisenberg Dyeing Liquids have been compared to its predicate device with regard to chemical composition, indications for use, and physical and mechanical properties (e.g. chemical solubility, strength, remission). The comparison for chemistry, indications for use, and performance data shows that Heisenberg Dyeing Liquids are substantially equivalent to the predicate device: Lava Frame Shade by 3M ESPE, Germany (K011394).

Biocompatibility testing was carried out.

In summary, it can be concluded that Heisenberg Dyeing Liquids are as safe and effective as the predicate device Lava Frame Shade by 3M ESPE, Germany (K011394).

### Indications for Use:

Heisenberg Dyeing Liquids are suited for the shading of Heisenberg zirconia frameworks and Heisenberg all-zirconia, monolithic restorations for anterior and posterior teeth.



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

3M Espe AG  
C/O Mr. Norbert Stuibler  
Responsible Third Party Official  
TÜV SÜD America, Incorporated  
1775 Old Highway 8 NW  
New Brighton, Minnesota 55112-1891

MAY 13 2011

Re: K111257  
Trade/Device Name: Heisenberg Dyeing Liquids  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder for Clinical use  
Regulatory Class: II  
Product Code: EIH  
Dated: April 29, 2011  
Received: May 4, 2011

Dear Mr. Stuibler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,



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):

K11257

Device Name:

Heisenberg Dyeing Liquids

Indications For Use:

Heisenberg Dyeing Liquids are suited for the shading of Heisenberg zirconia frameworks and Heisenberg all-zirconia, monolithic restorations for anterior and posterior teeth.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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