K103474

FEB - 7 2011

CONFIDENTIAL

510(k) Summary

Submitter: Mr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16036 Avegno (GE), Italy. Phone: +39 0185 7885 880.

I. Classification Name and Number: Crown And Bridge, Temporary, Resin (EBG 872.3770).

II. Common/Usual Name: Powder and liquid resin for temporary crowns and bridges.

III. Proprietary Name: ENA TEMP and ENAMEL PLUS TEMP (two different proprietary names for the same product).

IV. Registration No.: Foreign, in process

V. Compliance with Performance Standards: "ISO 20795" for denture materials and "ISO 10477" for crowns and bridges.

VI. Description of the Device: ENA TEMP/ ENAMEL PLUS TEMP is a system of liquid and powder resin available in different colours, for aesthetic temporary crown and bridge. It can be used both in laboratory (by indirect method: diagnostic waxing up or vacuum forming matrix) and in dental practice (by direct method in the mouth: silicone impression or preformed crown). Please note that the resin is absolutely the same, but they will be sold with two different brand names for commercial reasons. So, in order to simplify, from here on they will be denoted as "Temp"

VII. Labels and Labeling: Draft labels and instructions for use are provided.

VIII. Substantial Equivalence: K000894 - C&B RESIN PLUS POWDER/LIQUID, MODELS RETEMP A2, A3, A3.5, CL, RETEMP B2, B3, C2, D3, WH, RE by DENTAL VENTURES OF AMERICA, INC

VIII.1. Risk for health

1. Allergic reaction
2. No or incomplete stability
3. Gaps at tooth side if not tight
4. Secondary caries
5. Irritation of respiratory system and skin (only for liquid)

IX. Indications for Use: ENA TEMP/ ENAMEL PLUS TEMP is a system of liquid and powder resin available in different colours, for aesthetic temporary crown and bridge. It can be used both in laboratory (by indirect method: diagnostic waxing up or vacuum forming matrix) and in dental practice (by direct method in the mouth: silicone impression or preformed crown).

X. Premarket notification truthful and accurate statement.

(End of Summary)

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. Carla Tazzer
Quality Control
MICERIUM S.p.A.
Via Marconi, 83
16030 Avegno
ITALY

FEB - 7 2012

Re: K103474
Trade/Device Names: ENA Temp and Enamel Plus Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG
Dated: November 15, 2011
Received: November 26, 2011

Dear Dr. Tazzer:

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,

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

IX. Indications for Use [Separate Page] K103474

510(k) Number (if known): (not assigned)

Device Name: ENA TEMP, ENAMEL PLUS TEMP

Indications For Use:
ENA TEMP/ ENAMEL PLUS TEMP is a system of liquid and powder resin available in different colours, for aesthetic temporary crown and bridge. It can be used both in laboratory (by indirect method: diagnostic waxing up or vacuum forming matrix) and in dental practice (by direct method in the mouth: silicone impression or preformed crown).

Prescription Use __X___ **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)

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

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