

K111709

NOV 18 2011



UNIX-JAPAN CO., LTD.

5. 510(k) Summary

Trade/Proprietary name: Foundation Dental Resin

Common/usual name: Moldable Resin for dental use

Classification name Resin, denture, relining, repairing, or rebasing resin
21 CFR 872.3760
Product Code EBI

Summary (Equivalent Marketed Device)

This product is similar in function and intent of use to the Cosmetic Dental Materials, Inc.'s DuraFlex (K063626).

Intended Use

This provides a highly safe, molded article for fabricating molded articles for dental use having a definite shape to be used in the oral cavity and resin materials. Foundation Dental Resin is used to fabricate teeth and gums that are intended for use as removable full and partial dentures as well as occlusal splints and night guards.

This dental resin material is used by dental professionals including dentists and dental technicians. They can be used to make various sizes, shapes, and color shades for anterior and posterior preformed plastic teeth.

We are applying an approval as dental resin material as well as preformed product using this material.

Description of the Device Foundation Dental Resin material is a thermoplastic resin that is used to fabricate dental prosthesis. The resin is used in an injection molding or pressing device to fabricate the prostheses.

Foundation Dental Resin, which is characterized by the fact that the principal component is a copolymer polypropylene. Please see further details in COMPOSITION on page 19.



Safety and Effectiveness, comparison to predicate device:

The result of testing indicates that Foundation Dental Resin is as safe and effective as the predicate device.

- a) Safety Testing – Testing on genotoxicity, irritation, toxicity, cytotoxicity have been performed on this product to demonstrate compliance with following EN ISO standards. Based on the testing results, we conclude that this product is safe for the intended use. Please see attached for animal testing results.

This product is thermoplastic and does not use bisphenol A (BPA) which is used to make polycarbonate based dental resin. As this product does not contain BPA, it does not elude BPA.

Acrylic Resin generally contains PMMA (polymethylmetacrylate) and it is made of polymer (powder) monomer (liquid) by mixing in heat. After polymerization, residual monomer becomes a factor that elutes in the human body in the factor for causing an allergic reaction. On the other hand, based on anecdotal study for Foundation Dental Resin, there have not been any cases of allergic reactions.

- b) Effectiveness – Extensive testing has been performed on this product to demonstrate its effectiveness and characteristics appropriate for the intended use. Please see attached for Performance Data Document for intended use.

Technological Characteristics and Substantial Equivalence:

Foundations Dental Resin and predicate device are similar in design, material characteristics, physical properties, handling characteristics, intended use and functionality.

Performance and Safety testing:

Extensive testing has been performed on the Foundation Dental Resin to demonstrate compliance with the following EN ISO standards.



UNIX-JAPAN CO., LTD.

Please see Section 15. Biocompatibility on page. 21 and also attached actual test results on page. 26-65 for details.



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

Unix-Japan Company, Limited
C/O Ms. Toshiko Boyd
Managing Director
Eureka Global Solutions LLC
10920 Wilshire Boulevard, Suite 150
Los Angeles, California 90024

NOV 18 2011

Re: K111709
Trade/Device Name: Foundation Dental Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: October 24, 2011
Received: November 2, 2011

Dear Ms. Boyd:

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

K111709



UNIX-JAPAN CO., LTD.

4. Indication for Use Statement

Foundation Dental Resin is intended for use by a qualified/trained dentists or dental laboratory technicians on dental plates for dentures (false teeth), temporary crowns, artificial teeth and orthodontic devices.

Identification of the Device

Common name: Common name – Moldable Resin for dental use
Resin, denture, relining, repairing

Proprietary Trade Name: Foundation Dental Resin

Classification Name: Denture relining, repairing or rebasing resin.
21 CFR 872.3760

Class Class II

Product Code EBI

[Handwritten Signature] 11/17/11

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

510(k) Number: K11 1709