Paseo de la Estación, 4
28550 Tielmes (Madrid)
Tel. 91 873 76 30
Fax 91 874 64 90

unidesa
UNIÓN DENTAL S.A.

*(Premarket Notification [510(k)] Number: K070591)

510(k) SUMMARY

MAY 11 2007

Submitter

Company name: Union Dental S.A./ Unidesa.Odi

Address: Paseo de la Estación, 4
28550 Tielmes
Madrid, Spain

Contact name: José Luis Rodríguez
Telephone No. 011-34-91-873-76-30
Fax No. 011-91-874-64-90
e-mail: unidesa@unidesa-odi.com

Date of Summary: April 19th 2007

Device Name

Classification name: preformed plastic teeth.
Listed in Part 872- Dental Devices, Subpart D – Prosthetic Devices CFR Sec 872.3590

Proprietary name: Replica, Ortolux Top, Odipal, Odilux, Odident,Vitacrilic, Natures Best

Common name: Denture teeth

Predicate Devices

Heraeus Kulzer Artic plastic teeth (510K-K033628)
Dentsply Int. teeth (510K-K792245)
Nobelpharma Usa,Inc. teeth (510K-K915276)
Yamhachi. teeth (510K-K060507)
Artegral and polystar Selection teeth (510K-K030588)
Artic teeth (510K-K033628)
Trilux, Z-tone, Acryrock teeth (510K-K022299)
Acry Pan, Vipi Dent Plus, teeth (510K-K022300)
Wiedent Estetic teeth (510K-K061337)

The device is similar in size, shape, color, chemical composition and usage as the above products.

*(Premarket Notification [510(k)] Number: K070591) **510(k) SUMMARY (cont.)**

Devices description

A preformed plastic denture tooth is a prefabricated device, composed of Polymethyl Methacrylate. The teeth are made up of several different acrylic resins that form the layers of enamel, dentine and neck, all of which are created using the polymerization of acrylic monomers, reticulant agents, resins and non-toxic pigments that form a unique composition, which with the union of the layers produces a compact whole that looks and behaves in a similar way to real teeth.

Once the polymerization process has been carried out, the teeth are obtained and the next step is to remove any burrs and polish them. They are then mounted in the presentation units with the relevant product details (brand, model, colour and batch).

Intended use

It is intended for use as a tooth in a denture.

These teeth are used for making full or partial dentures. The artificial resin teeth are mounted on an appliance made of dental acrylic resin. The appliance is made to fit the patients mouth and is a removable. It is not implanted.

Technological characteristic and substantial equivalence

- The device has comparable chemical composition as the predicate devices.
- The device is similar in size, shape, color and usage as the above predicates devices.

The labeling includes the proprietary name, the shade which is comparable to competitors such as Dentsply, Heraeus Kulzer, Vita Zahnfabrik, Nobelpharma, Heraeus Kulzer, Vipi, and Merz Dental and a mold number which can be used to pick out the proper sized tooth for the patient.

Performance Testing

The device is tested according to ISO 3336:1993, Dentistry-Synthetic Polymer Teeth(Dental/ENT) which is similar to ISO ADA Specification No. 15:1999 Synthetic Resin Teeth and are Recognized Consensus Standards, Recognition List Number 007. Effective Date 05/31/2002

Testing also includes biocompatibility tests and clinical evaluation of health products in application of the directive 93/42/EEC. Annex X -. Option I.

Conclusions: The device is safe and effective to be used as denture teeth and is substantially equivalent to the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. José Luis Rodríguez
Technical Director
Union Dental S.A./ Unidesa. Odi
Paseo de la Estación, 4
28550 Tielmes
Madrid, Spain

MAY 11 2007

Re: K070591
Trade/Device Name: Replica, Ortolux Top, Odipal, Odilux, Odident Vitacrilic
Natures Best. Dental Acrylic Teeth
Regulation Number: 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: April 19, 2007
Received: April 23, 2007

Dear Mr. Rodríguez:

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.

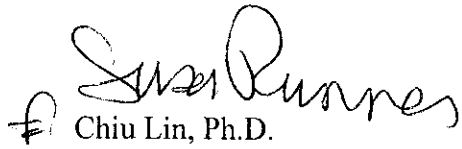
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

K070591

Indications for Use

510(k) Number (if known): K070591)

Device Name: Replica, Ortolux Top, Odipal, Odilux, Odident,Vitacrilic, Natures Best. Dental acrylic teeth.

Indications For Use:

Teeth for the fabrication of dentures

These teeth are used for making full or partial dentures. The artificial resin teeth are mounted on an appliance made of dental acrylic resin. The appliance is made to fit the patients mouth and is a removable. It is not implanted.

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)

Susan Runner

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

510(k) Number: K070591