K060507

510(k) Summary
for
Valplast Yamahachi Teeth

1. SPONSOR

APR 7 2006

Valplast International Corp.
34-30 31st Street
Long Island, NY 11106

Contact Person: Peter Nagy
Telephone: 1-718-361-7440

Date Prepared: February 23, 2006

2. DEVICE NAME

Proprietary Name:	Yamahachi Teeth
Common/Usual Name:	Dentures
Classification Name:	Plastic preformed teeth for dentures

3. PREDICATE DEVICES

Heraeus Kulzer, Inc., Artic Plastic Teeth Dentures subject of K033628

Merz Dental GmbH Artegral and Polystar Selection Preformed Plastic Teeth subject of K030588

4. DEVICE DESCRIPTION

The Yamahachi Teeth are anterior and posterior teeth that are intended to be used in removable dentures only. They are made up of three synthetic polymers including polymethlymethacrylate, polymethylmethacrylate-SiO_2, and a composite resin urethane dimethacrylate-polymethylmethacrylate - SiO_2. The Yamahachi Teeth are used in conjunction with a denture-base resin for construction of removable full and partial dentures. The teeth are intended to be used by dental professionals such as dentists and dental technicians. The Yamahachi line of teeth include various sizes, shapes, and shades of anterior and posterior preformed plastic teeth

5. INTENDED USE

The Valplast Corporation Yamahachi Teeth are prefabricated, preformed plastic teeth that are intended for use as teeth in removable dentures.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Yamahachi teeth are essentially identical to the predicate devices in that they are all made from methylmethacrylate or a derivative of methylmethacrylate. The proposed and predicate devices are offered in various sizes, shapes, and colors. Like the predicate devices, the Yamahachi Teeth are artificial resin teeth that are compatible with all denture base resins.

7. PERFORMANCE TESTING

Extensive testing has been performed on the Yamahachi Teeth to demonstrate compliance with EN ISO 3336:1997 Dentistry; Synthetic polymer teeth; EN ISO 7405:1997 Dentistry; Preclinical evaluation of biocompatibility of medical devices used in dentistry, Test methods for dental materials; EN ISO 1567:1995 Denture Base Polymers; EN ISO 3950:1997 Dentistry-Designation system for teeth and areas of the oral cavity; and EN ISO 7491:2000 Dental Materials-Determination of color stability of dental polymeric materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Valplast International Corporation
C/O Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K060507
Trade/Device Name: Yamahachi Teeth
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: February 23, 2006
Received: February 28, 2006

Dear Ms. McNamara-Cullinane:

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" (21 CFR 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 S. Lin, PhD
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): K060507

Device Name: Valplast Yamahachi Teeth

Indications for Use: The Valplast International Corporation Yamahachi Teeth are prefabricated, preformed plastic teeth that are intended for use as teeth in removable dentures.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General Hospital Devices

K060507