

K101029  
**510(k) Summary**

**Summary Prepared Date:** 03/26/2010

**Submission Sponsor:**

AUG 16 2010

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**Submission Correspondent:**

Mr. Leon Lu  
Director of Regulatory Affairs

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**Trade/Device Name:** SYNTHETIC POLYMER TEETH (Kaifeng/Crystal, Kaili, Kaijing, Kaiyue, MAIST and Kaitong/Royal)

**Common or Usual Name:** Preformed Plastic Denture Teeth

**Device Class:** II

**Classification Name:** Preformed Plastic Denture Tooth

**Regulation Number:** 21 CFR 872.3590

**Product Code:** ELM

**Review Panel:** Dental

**Predicate Device:**

- K061337, XPDENT CORPORATION  
WIEDENT ESTHETIC TEETH
- K070591, UNION DENTAL S.A./UNIDES.A.ODI  
REPLICA, ORTOLUX TOP, ODIPAL, ODILUX, ODIDENT, VITACRILIC, NATURE'S  
BEST, DENTAL ACRYLIC TEETH
- K022300, DENTAL VIPI LTDA  
ACRY PAN, VIPI DENT PLUS, BIOLUX, BIOLUX V, NEW DENT, DENTOLUXX, VIPI  
DENT N.H., VIPI DENT V PERFORMED PLASTIC DENTURE TEETH

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

**Device Description:**

The Synthetic Polymer Teeth (Kaifeng/Crystal, Kaili, Kaijing, Kaiyue, MAIST and Kaitong/Royal) used in the production of dentures are produced through a dough molding process. Polymethylmethacrylate (PMMA) is mixed with methylmethacrylate monomer and a cross-linking agent.

Once the polymerization process has been carried out, the teeth are obtained and the next step is to remove any burrs and polish them.

**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 patient's mouth and is a removable. It is not implanted.

**Comparison to Predicate Devices:**

The device has comparable chemical composition as the predicate devices.

The device is similar in size, shape, color and usage as the predicate devices.

**Discussion of Non-Clinical Tests Performed:**

Performance and safety testing activities were conducted against recognized standards to establish the reliability characteristics of the new devices. Testing involved bench studies, and biocompatibility tests.

**Discussion of Clinical Tests Performed:**

None

**Conclusion:**

The proposed device is as safe and effective as the predicate devices. The proposed device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the proposed device and its predicate devices raise no new issues of safety or effectiveness. Thus, the Synthetic Polymer Teeth (Kaifeng/Crystal, Kaili, Kaijing, Kaiyue, MAIST and Kaitong/Royal) is substantially equivalent to its predicate devices.

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

Huge Dental Material Company, Limited  
C/O Mr. Jing Li  
MEDevice Services, LLC  
3500 South Dupont Highway  
Dover, Delaware 19901

AUG 16 2010

Re: K101029

Trade/Device Name: SYNTHETIC POLYMER TEETH (Kaifeng/ Crystal, Kaili,  
Kaijing, Kaiyue, MAIST and Kaitong/ Royal)

Regulation Number: 21 CFR 872.3590

Regulation Name: Preformed Plastic Denture Tooth

Regulatory Class: II

Product Code: ELM

Dated: July 12, 2010

Received: July 22, 2010

Dear Mr. Li:

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

K 101029

## Indications for Use

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

Device Name: SYNTHETIC POLYMER TEETH (Kaifeng/Crystal, Kaili, Kaijing, Kaiyue, MAIST and Kaitong/Royal)

**Indications for 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 patient's mouth and is a removable. It is not implanted.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mubey for MSR  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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