K060720 AUG 25 2006

510(k) Premarket Notification
for the
Curative Dental Acrylic Teeth

1. COMPANY NAME AND ADDRESS

1.1 Sponsor

Curative, LLC
2275 East Bayshore Road, Suite 105
Palo Alto, CA 94303
Telephone: 650-856-9600
Facsimile: 650-856-9601

1.2 Manufacturer

Shanghai Dental Materials Factory
Shanghai Medical Instruments Co., Ltd
No. 690 Tian Tong An Road
Shanghai, China, 200081
Telephone: 86-21-56664470
Facsimile: 86-21-65402339

1.3 Consultant/Contact

Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Primary Contact: James R. Veale
Telephone: 719-495-3438
Facsimile: 719-495-3438

2. DEVICE NAME

Proprietary Name: Curative Dental Acrylic Teeth
Common/Usual Name: Acrylic Denture Teeth
Classification Name: Preformed plastic denture tooth (21CFR 872.3590)

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Curative Dental Acrylic Teeth are intended for the same purpose as the predicate products, and are made of the same or similar materials.

7. PERFORMANCE TESTING

Data were provided to demonstrate that the Curative Dental Acrylic Teeth comply with applicable safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2006

Curative, LLC
C/O Mr. James R. Veale
Senior Technical Adviser
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K060720
Trade/Device Name: Curative Dental Acrylic Teeth
Regulation Number: 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: July 27, 2006
Received: July 28, 2006

Dear Mr. Veale:

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

510(k) Number: K060720

Device Name: Curative Dental Acrylic Teeth

Indications For Use:

Curative Dental Acrylic Teeth are preformed plastic denture teeth intended for use as teeth in 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 NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mulay for MJR

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

510(k) Number: K 060720