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Prep Technology Corp.

K97 4655

510(k) PrepTech Cavity Preparation System, Nov. 15, 1997

**510(k) Summary of Safety and Effectiveness  
Prep Technology Corp.  
PrepTech 200™ Cavity Preparation System**

**Statement of Intended Use:**

The Prep Technology Corp. PrepTech 200™ Cavity Preparation System is intended for use in cavity preparation for bonded restorations, the removal of decayed or sound tooth structure and composite restoration materials and for the preparation of tooth surfaces prior to pit and fissure sealant and composite restorations.

**Submitted by:**

Prep Technology Corp.  
43204 Christy Street  
Fremont, CA 9538  
Tel: 510.440.8800  
Fax: 510.440.8797

**Contact Person:**

Joe W. Shaffer  
President  
Telephone: 510.440.8800

**Date Summary Prepared:**

November 15, 1997

**Name of the Device:**

Proprietary Name: PrepTech 200™ Cavity Preparation System  
Common/Usual Name: Air Abrasive System for Dental Applications  
Classification Name: Airbrush (per 21 CFR 872.6080)

**Predicate Devices:**

Danville Engineering PrepStar Cavity Preparation System  
Sunrise Technologies MicroPrep Cavity Preparation System

**Description:**

The Prep Technology Corp. PrepTech 200 Cavity Preparation System is a device that combines pressurized air and aluminum oxide powder to produce a high velocity stream of kinetic particles to perform dental restorative procedures, including preparation for pit and fissure sealants and composite restorations.

**Comparison to Predicate Devices:**

The PrepTech 200 Cavity Preparation System has been compared to legally marketed devices with respect to intended use and technological characteristics. The comparison results presented in this 510(k) notification to the FDA show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Joe W. Shaffer  
President  
Prep Technology Corporation  
43204 Christy Street  
Fremont, California 94538

Re: K974655  
Trade Name: PrepTech 200™ Cavity Preparation System  
Regulatory Class: III  
Product Code: KOJ  
Dated: November 15, 1997  
Received: December 15, 1997

Dear Mr. Shaffer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

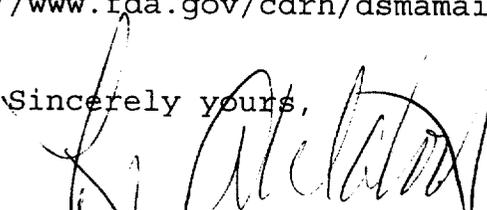
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): Not Yet Assigned

Device Name: Prep Technology Corp. PrepTech™ 200 Cavity Preparation System

Indications For Use:

The Prep Technology Corp. PrepTech 200 Cavity Preparation System is intended for use in cavity preparation for bonded restorations, the removal of decayed or sound tooth structure and composite restoration materials and for the preparation of tooth surfaces prior to pit and fissure sealant and composite restorations.

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

*Susan Pinner*

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number KA 74635

Prescription Use  OR Over-The-Counter Use   
(Per 21 CFR 801.109)

(Optional Format 1-2-96)