

K072830



6.0 510(K) SUMMARY

DEC 04 2007

Pentron Clinical Technologies, LLC.
68 North Plains Industrial Road
Wallingford, CT 06492
Tel: 203-265-7397
Fax: 203-284-4986
Contact: Greg Moreau

Trade Name:	RM Bond Adhesive
Common Name:	Bracket Adhesive
Classification Name:	Adhesive, Bracket & Tooth Conditioner, Resin, 21CFR 872.3275, DYH

RM Bond Adhesive product performs the same intended function as its predicate device, APC Plus Adhesive (reference K020394), for orthodontic appliance applications. Both devices are intended for indirect bonding of appliance materials to teeth in order to facilitate orthodontic treatment.

The subject device is a light-cured resin adhesive in a methacrylate-based formulation; the light curing feature provides the clinician appropriate flexibility for bracket placement working-time considerations.

Product is supplied as refills in a variety of delivery systems; multi-use bottle or syringe as well as a single dose delivery system.

A review for safety and effectiveness was performed and found not to have been affected.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 04 2007

Mr. Greg Moreau
Director, Quality Systems
Pentron Clinical Technologies, LLC
68-70 North Plains Industrial Road
Wallingford, Connecticut 06492

Re: K072830

Trade/Device Name: RM Bond Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH, EBF
Dated: September 28, 2007
Received: October 3, 2007

Dear Mr. Moreau:

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.

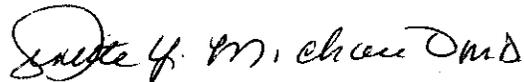
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K072830

DEVICE NAME: RM Bond Adhesive

INDICATION FOR USE:

RM Bond Adhesive product is indicated for orthodontic appliance applications using an indirect bonding treatment technique.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR Over -The-Counter-Use
 (Optional Format 1-2-96)

Susan R. ...
Special Representative
Office of Anesthesiology and Pain Management
Center for Devices and Radiological Programs

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