

2/23/99

K9910252



SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.  
1717 W. Collins Avenue  
Orange, California 92867  
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Colleen Boswell - Contact Person

Date Summary Prepared: January 1999

Device Name:

- Trade Name - Solo Plus Ortho
- Common Name - Orthodontic Bonding Primer
- Classification Name - Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR § 872.3750

Devices for Which Substantial Equivalence is Claimed:

- Unitek Corporation/3M, *Transbond MIP Moisture Insensitive Primer*

Device Description:

The device is a universal primer for labial and lingual bonding of ceramic or metal brackets. Solo Plus Ortho may be light cured, using Solo Plus Ortho Primer A, or chemical cured using Solo Plus Ortho Primer A and Solo Plus Ortho Primer B.

Intended Use of the Device:

The intended use of Solo Plus Ortho is as an enhancing primer for labial and lingual orthodontic bonding.

Substantial Equivalence:

Solo Plus Ortho is substantially equivalent to other legally marketed devices in the United States. The orthodontic bonding primer marketed by Unitek Corporation/3M functions in a manner similar to and is intended for the same use as the product manufactured byOrmco Corporation.



FEB 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Colleen Boswell  
Senior Regulatory Affairs Specialist  
Sybron Dental Specialties, Incorporated  
1717 W. Collins Avenue  
Orange, California 92867

Re: K990252  
Trade Name: Solo Plus Ortho  
Regulatory Class: II  
Product Code: DYH  
Dated: January 25, 1999  
Received: January 27, 1999

Dear Ms. Boswell:

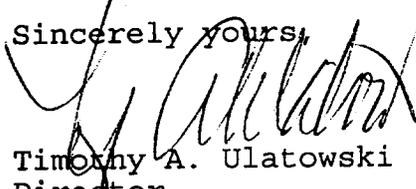
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market notification submission does not affect any obligation you might have under sections 531 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) 594-4692. 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

