



K994309

SYBRON DENTAL SPECIALTIES

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

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
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Wendy Urtel - Contact Person

Date Summary Prepared: December 1999

Device Name:

- Trade Name – Solo Ortho 2
- Common Name - Orthodontic Bonding Primer
- Classification Name - Bracket Adhesive Resin and Tooth Conditioner, per 21 CFR § 872.3750

Device for Which Substantial Equivalence is Claimed:

- *Solo Plus Ortho* –Ormco Corporation

Device Description:

The device is a one-bottle, universal primer for labial and lingual bonding of ceramic or metal brackets. Solo Ortho 2 can be used with either chemical or light cured adhesive systems.

Intended Use of the Device:

The intended use of Solo Ortho 2 is as an enhancing primer for labial and lingual orthodontic bonding.

Substantial Equivalence:

Solo Ortho 2 is substantially equivalent to other legally marketed devices in the United States. Solo Ortho 2 functions in a manner similar to and is intended for the same use as the product Solo Plus Ortho cleared for marketing for Ormco Corporation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 17 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Wendy Urtel
Senior Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K994309
Trade Name: Solo Ortho 2
Regulatory Class: II
Product Code: DYH
Dated: December 16, 1999
Received: December 21, 1999

Dear Ms. Urtel:

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.

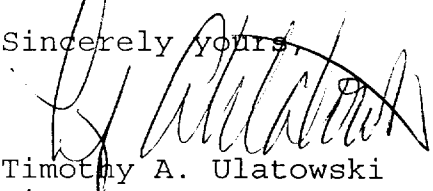
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 premarket 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.

Page 2 - Ms. Urtel

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

Section I - Indications for Use

510(k) Number: K994309

Device Name: Solo Ortho 2

Indications for Use:

Solo Ortho 2 is designed to be used as an enhancing primer for labial and lingual orthodontic bonding.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994309