

K972890

510 (k) Summary**Statement of Safety and Effectiveness****Ormco Enlight Orthodontic Adhesive**Submitter

Sybron Dental Specialties Inc.
1717 West Collins Avenue
Orange, CA 92867
(714) 516-7486 - Phone
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William R. Pike - Contact Person

Device Name

Trade Name: Enlight (Tentative Name)

Common Name: Visible Light Cured Orthodontic Bracket Adhesive and Sealant

Classification Name: DYH DE(76) Adhesive, Bracket and Tooth Conditioner, Resin Class II

Devices for which Substantial Equivalence is Claimed

Unitek Transbond (3M) and Light - Bond (Reliance Orthodontic Products, Inc.)

BACKGROUND

Methacrylate ester monomer based adhesives have been used successfully for over thirty years to bond appliances to teeth during orthodontic treatment procedures. Early examples of these products were chemically cured (autocure) materials that required the mixing of a catalyst and base resin by the orthodontist immediately prior to positioning the bracket on the tooth. Because the working time of these materials was so unpredictable due to the effects of temperature and aging, many times the orthodontist would have to reposition the appliance and repeat the bonding process.

In 1992, Ormco Corporation introduced a product, "Sequence" (FDA Reference No. K914627) that employed a visible light curing initiation system for curing. Sequence was not time dependent and allowed the orthodontist to correctly position the bracket before curing with a 10 -20 second exposure to intense visible light. It is the next generation of visible light curing orthodontic adhesives that is the subject of this 510 (k) submission.

Enlight Orthodontic Adhesive and Sealant

Ormco's Enlight is designed to fulfill all of the requirements of a successful orthodontic adhesive. These requirements are itemized below:

1. Ease of placement: optimized resin blend that exhibits superb handling characteristics.
2. Convenience: Both syringe and Unidise delivery systems are available.

3. Enlight provides fluoride release for caries protection during the orthodontic treatment period.

SAFETY

The safety of Ormco Enlight adhesive has been demonstrated by subjecting cured samples of the material to three biocompatibility tests as recommended in the ISO 10993 biocompatibility guidance standard. This testing was conducted by an independent laboratory which specializes in safety and toxicity evaluation.

1. Test Type: Cytotoxicity Study (Agarose Overlay)
2. Test Type: Mucosal irritation in the rabbit vagina.
3. Test Type: Dermal Contact sensitization (Guinea Pig)

EFFICACY

Effectiveness or suitability to the intended purpose of Enlight has been demonstrated by a combination of in-house testing and side by side test comparisons to predicate devices currently on the market. Results of this bench testing indicates that Ormco Enlight Orthodontic Adhesive performs as well or better than the predicate devices currently on the market



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1997

Mr. William R. Pike
Regulatory Affairs Specialist
Sybron Dental Specialities, Incorporated
1717 W. Collins Avenue
Orange, California 92667

Re: K972890
Trade Name: Enlight (Tentative Name)
Regulatory Class: II
Product Code: DYH
Dated: July 30, 1997
Received: August 5, 1997

Dear Mr. Pike:

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 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

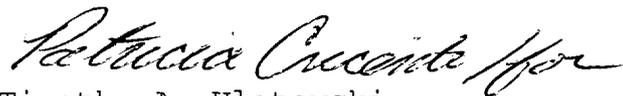
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 : K 972890

Device Name : **Enlight Orthodontic Bracket Adhesive**

Indications For Use : Ormco Enlight is a single component sealant and single component paste, visible light cured orthodontic bonding adhesive indicated for the attachment of orthodontic appliances to teeth.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 972890

Prescription Use
(Per 21 CFR 801.109)