DEC 1 6 2003

K033551

Section 7
SPECIAL 510 (k) SUMMARY

1. **Applicant:** Reliance Orthodontic Products, Inc.
1540 W. Thorndale Ave
Itasca, IL 60143

Contact Person: Benjamin Lichtenwalner
Ph. 847-534-6146
Fax 847-534-6111

Date Prepared: November 7, 2003

2. **Trade Name:** EVOLVE
Common/Usual Name: Dental Orthodontic Adhesive
Classification/Name: Class II per 21 CFR 872.3750/Bracket adhesive resin and tooth conditioner

3. **Predicate (un-modified) Device**: Light Bond with Fluoride, cleared under K895522 dated 12/7/1989

4. **Description of Applicant Device:**
EVOLVE is a fluoride-releasing, light-cured, color changing bracket bonding adhesive for use with any type of orthodontic bracket in bonding to any enamel, porcelain, composite or metal surfaces when properly conditioned. It is a highly filled, smooth, tacky paste that helps prevent bracket flotation and delivers maximum bond strength on curing. Its contrasting blue color facilitates the ease of placement and removal of excess and changes to natural (beige) when cured. The material is supplied in push syringes or syringe tips.

5. **Intended Use of Applicant Device:**
EVOLVE is a fluoride-releasing, light-cured orthodontic bracket bonding system to be used in the oral cavity of dental patients. The intended use, dental bracket bonding, of EVOLVE is identical to the un-modified (predicate) device Light Bond with Fluoride.

6. **Technological Characteristics:**
EVOLVE posses the same technological characteristics as the un-modified (predicate) device, Light Bond with Fluoride and has similar physical properties. Below is a table which shows a side-by-side comparison of the technological characteristics.

Technological Characteristics	Evolve	Light Bond with Fluoride
Intended use	Dental Bracket Adhesive	Dental Bracket Adhesive
Chemical Composition	Light cured, fluoride-releasing, glass filled, Dimethacrylate-based composite	Light cured, fluoride-releasing, glass filled, Dimethacrylate-based composite
Mechanical /physical properties	Highly viscous, smooth, tacky paste. High bond strength	Highly viscous, smooth, tacky paste. High bond strength

EVOLVE was tested for biocompatibility and it was found to be non-toxic. It is concluded that the information supplied in this submission has proven that EVOLVE is as safe and effective as Light Bond with Fluoride for the intended use. The proposed changes do not affect the safety and efficacy of the modified product, EVOLVE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2003

Reliance Orthodontic Products, Incorporation
C/O Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporation
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K033551
Trade/Device Name: EVOLVE
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: December 03, 2003
Received: December 08, 2003

Dear Mr. Lichtenwalner:

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 (301) 594-4618. 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known):**K033551**

Device Name: **EVOLVE**

Indications For Use:

1. Fluoride-releasing, light-cured bracket bonding system in the oral cavity of dental patients.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033551