



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 24 1998

Mr. H.J. Vogelstein  
Coltene/Whaledent, Incorporated  
750 Corporate Drive  
Nahwah, New Jersey 07430

Re: K974906  
Trade Name: One Coat Bond Dentin/Enamel Adhesive System  
Regulatory Class: II  
Product Code: KLE  
Dated: March 12, 1998  
Received: March 13, 1998

Dear Mr. Vogelstein:

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

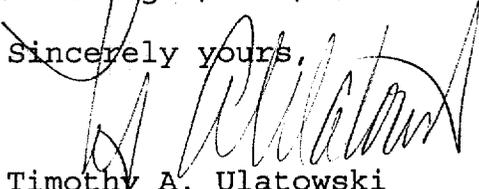
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Number (if known): K974906

**One Coat Bond Dentin/Enamel Adhesive System**

Device Name: \_\_\_\_\_

**510(k) Submission**

**Indications For Use**



Coltène/Whaledent Inc.  
750 Corporate Drive  
Mahwah, NJ 07430  
Telephone: 201-512-8000

**Definition**

Coltène® ONE COAT BOND is a light-cured, multi-purpose, one-component adhesive agent for adhesive restoration techniques in dentistry. Coltène® ETCHANT 15 is a gel used for etching of dentine and enamel before the application of coltène® ONE COAT BOND.

**Composition**

Coltène® ONE COAT BOND contains:

- Hydroxyethyl methacrylate
  - Hydroxypropylmethacrylate
  - Glycerinedimethacrylate
  - Polyalkenoate methacrylized
  - Urethanedimethacrylate
  - Amorphe silicic acid
- HEMA

Coltène® ETCHANT 15 contains:

Water, phosphoric acid 15%, gel former

Susan Purnas

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

510(k) Number K974906

**Indications**

Bonding adhesive restoration techniques.

Direct filling technique:

- Adhesive bonding of composite materials to natural enamel and dentine (coltène® SYNERGY, coltène® Brilliant Dentin/Enamel/Incisal).

Indirect restorative techniques:

- Adhesive bonding of ceramic and composite patterns with coltène® Duo Cement to natural enamel and dentine.

Adhesive bonding of other dental materials:

- composite materials to pretreated ceramics
- composite material to composite material
- composite material to pretreated metals
- dentine sealing

Sclerotic dentin:

- Use 35 % phosphoric acid for 30 s (e.g. coltène® Etchant Gel S)

**Contra-Indications**

Allergy exist to any of the components of coltène® ONE COAT BOND and coltène® ETCHANT 15. If the site cannot be isolated after enamel etching and during application and curing of coltène® ONE COAT BOND. If oral hygiene is poor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No