K092616

510(k) Summary of Safety and Effectiveness

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Robert K. Larsen, Regulatory Affairs Manager
Preparation Date: August 14, 2009

OCT 21 2009

Device Name:

Trade Name:	Ascent Bond Universal Adhesive System
Common Name:	Dental adhesive
Product Classification:	Agent, Tooth Bonding, Resin (21 CFR 872.3200, Product Code: KLE)

Legally Marketed Predicate Devices for Substantial Equivalence:

- Ascent Universal Adhesive, Manufactured by CAO Group, Inc.
  510(k) Number: K070413
- Gluma Comfort Bond + Desensitizer, Manufactured by Heraeus Kulzer, Inc.
  510(k) Number: K992292

Rationale for Substantial Equivalence:

The aforementioned device shares similarities for use in the oral environment for the purpose of adhering restorative materials to tooth structure. This device features similar indications for use, ingredients, and application methods to the predicate devices.

Description of Submitted Device:

The Ascent Bond Universal Adhesive is an ethanol-based composition containing a special formulation of resins to achieve an excellent bond to materials such as restorative composites, dentin, enamel, metals and porcelain. The composition is polymerized by means of a dental polymerization light source. Exact information regarding the material's constituents is found in Part 6: Specifications

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Intended Uses of the Ascent Bond Universal Adhesive System:

Ascent Bond Universal Adhesive System is indicated for direct bonding to and desensitizing of dentin and enamel, and direct bonding to composite, porcelain, and base metals.

Technological Characteristics of Substantial Equivalence:

Both the submitted and predicate devices are composed of similar substances, with similar active constituents in similar concentrations. Both have similar indications for use. Both have similar methods of application. Both are used in conjunction with dental restorative and preventative procedures.

Performance Standards:

None

Performance Data

See Part 7: Performance Data

Conclusion

The Ascent Bond Universal Adhesive System is substantially equivalent to the aforementioned predicate device with regards to purpose of the device, general composition, methods of application, and indications for use without raising any new issues regarding safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert K. Larsen
Regulatory Affairs Manager
CAO Group, Incorporated
4628 West Skyhawk Drive
West Jordan, Utah 84084

OCT 21 2009

Re: K092616
Trade/Device Name: Ascent Bond Universal Adhesive System
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and LBH
Dated: August 14, 2009
Received: August 26, 2009

Dear Mr. Larsen:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting 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): K092616

Device Name: *Ascent Bond Universal Adhesive System*

Indications For Use:

Ascent Bond Universal Adhesive System is indicated for direct bonding to and desensitizing of dentin and enamel, and direct bonding to composite, porcelain, and base metals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)

Kevin Mulloy for MSR

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

510(k) Number: K092616