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K070070

510(k) Summary of Safety and Effectiveness

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Robert K. Larsen, Operations Director
Preparation Date: May 14, 2007

MAY 25 2007

Device Name:

Trade Name:	Ascent Dental Cleanser
Common Name:	Dental cleansing material
Product Classification:	Varnish, Cavity (21 CFR 872.3260, Product Code: LBH)

Legally Marketed Predicate Devices for Substantial Equivalence:

- Chloraprep, Manufactured by Centrix, Inc.
  510(k) Number: K021131

Rationale for Substantial Equivalence:

The aforementioned device shares similarities for the purpose of cleansing cavities in conjunction with dental restorative procedures. This device features similar indications for use and application methods to the predicate device.

Description of Submitted Device:

The Ascent Dental Cleanser is a water-based tooth cavity preparation cleanser containing chlorhexidine gluconate and a solvent. This composition, when introduced into a cavity preparation, works to dislodge unwanted and/or foreign material. The cleanser is dispensed from a prefilled applicator directly to the desired site. The applicator may be in the form of a one-time unit dose configuration, or may be supplied in a larger prefilled quantity that accommodates single-use disposable tips of varying size and length to accommodate the needs of a particular procedure. Exact information regarding the material's constituents is found in Part 8: Biocompatibility Assessment.

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Intended Uses of the Ascent Dental Cleanser:

The Ascent Dental Cleanser is intended for cleaning and disinfecting cavity preparations in conjunction with dental restorative procedures. The water-based preparation, when introduced into a cavity preparation, works to dislodge unwanted and/or foreign material. The amount of time the material is introduced at the site is determined by the dental professional as dictated by the location of the site and the extent of cleansing that is required. This material is used independently or in conjunction with other devices to achieve the level of cleansing desired.

Technological Characteristics of Substantial Equivalence:

Both the submitted and predicate device 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 procedures. A comparison table of the predicate device and submitted device is contained in Part 7: Performance Data.

Performance Standards:

None

Performance Data

See Part 7: Performance Data

Conclusion

The Ascent Dental Cleanser 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert K. Larsen
Operations Director
CAO Group, Incorporated
4628 West Skyhawk Drive
West Jordan, Utah 84084

MAY 25 2007

Re: K070070
Trade/Device Name: Ascent Dental Cleanser
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: May 14, 2007
Received: May 15, 2007

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 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K070070

Indications for Use

510(k) Number (if known): K070070

Device Name: *Ascent Dental Cleanser*

Indications For Use:

Ascent Dental Cleanser is indicated for:

- The cleansing and disinfecting only of tooth cavity preparations in conjunction with dental restorative procedures

(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 RSE

ospital,

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