DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2001

Mr. Cesar E. Veliz
Official Correspondent
Rite-Dent Manufacturing Corporation
1056 East 33rd Street
Hialeah, Florida 33013-3526

Re: K003427
Trade Name: Zinc Phosphate Cement
Regulatory Class: II
Product Code: EMA
Dated: October 27, 2000
Received: November 3, 2000

Dear Mr. Veliz:

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 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). 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 Current Good Manufacturing Practice requirements, 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

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) 594-4692. 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" (21CFR 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/dsma/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

Rite-Dent Mfg. Corp.
1056 East 33rd Street
Hialeah, FL 33013
Establishment # 1064592

INDICATIONS FOR USE

510 (K) Number: Unknown K003427

Device Name: Zinc Phosphate Cement

Indications for Use:

Zinc Phosphate is the oldest of the cementation agents and thus the one with the longest track record (introduced in 1878). It serves as a standard by which newer systems can be compared. It consists of powder and liquid in two separate bottles. The main ingredients of the powder are zinc oxide and magnesium oxide. The liquid contains phosphoric acid distilled water, alumina hydride, and zinc oxide. Zinc phosphate cement is without any adhesive properties and is used as a luting agent. It is always referred to as cement and is used for the attachment of indirect restorations and appliances to the teeth and for the cementation of inlays, onlays, crowns, temporary fillings, bridges, facings, and orthodontic brackets.

Prescription Use ✓

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and General ...
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