DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2001

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

Re: K010255
Trade/Device Name: Cavity Varnish
Regulation Number: 872.3260
Regulatory Class: II
Product Code: LBH
Dated: January 25, 2001
Received: January 29, 2001

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,

Patricia Cucente/for

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

**Device Name:** Cavity Varnish

**Indications for Use:**

**Cavity Varnish:**

Rite-Copal is a desensitizing cavity varnish and dentinal sealer, which is used for sealing cavities before restorations after scaling, prophylaxis, and cavity preparation and prior to any cementation and pin or post seating. It provides a hard protective barrier against the penetration of irritants from cements or other restorative materials and it reduces the penetration of oral fluids at the restoration-tooth interface into the underlying dentin. It minimizes marginal leaks and acts as a thermal insulator. Rite-Copal also minimizes postoperative sensitivity when applied to dentinal surfaces under newly placed restorations.

Rite-Copal is to be used by dental professionals to control thermal shock and sensitivity in teeth undergoing treatment or restoration. It can be used under veneers, inlays, crowns, onlays, amalgams and composite resins and to treat cervical or root sensitivity.

Rite-Copal is made from materials that the scientific community has deemed to be safe in this application for over 25 years.

Susan Runner
(Sign-Off)
Dental, Infection Control,
General Hospital Devices
Number K012355