NOV 19 1999

510(k) Summary

Super Glide, Incorporated

Name & Address:

K992919

Super Glide, Inc.
225 Colchester Avenue
Burlington, VT 05401
PH: 1-800-655-1777
Fax: 1-802-864-0201
FDA Reg. No. 1223133

CONTACT: Victor L. Ratkus, D.D.S.

DATE PREPARED: August 30, 1999

TRADE OR PROPRIETARY NAME: Oxy Glide™

CLASSIFICATION NAME: Root Canal Cleanser / Lubricant

PREDICATE DEVICE: RC-PREP Pre-1976 Device

DEVICE DESCRIPTION: Oxy Glide™ allows for cleansing action that facilitates easy removal of vital pulp tissue and necrotic pulp tissue from the root canal. It is designed to be used with endodontic irrigation with sodium hypochlorite solutions. Oxygen bubbling occurs through the release of oxygen from the urea peroxide. This action allows for the pulp tissue, dentinal shavings, and debris to float out.

The physical properties of Oxy Glide™ and the predicate device are similar, i. e., viscosity, appearance, color, and odor.
The intended use of Oxy Glide™ and the predicate device are the same, i.e., the cleansing and preparation of the root canal.

INTENDED USE: Oxy Glide™ is used in the chemical and mechanical cleansing of the root canal preparation during endodontic therapy.

TECHNOLOGICAL CHARACTERISTICS: The active ingredient in Oxy Glide™ and other components have been used in predicate medical devices and/or have been found safe for dental use.

We believe that, due to the long established safe and efficacious use of the predicate device in the same intended use, the same active ingredient, the short duration of contact within the oral cavity, and the decomposition and thorough removal of the product from the canal space, the use of Oxy Glide™ does not require additional biocompatibility testing and that Oxy Glide™ is safe for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Victor L. Ratkus, D.D.S.
President
Super Glide, Inc.
227 Colchester Avenue
Burlington, Vermont 05401

Re: K992919
Trade Name: Oxy Glide™ Root Canal Cleanser and Lubricant
Regulatory Class: Unclassified
Product Code: KJJ
Dated: August 30, 1999
Received: August 30, 1999

Dear Dr. Ratkus:

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 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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(AS REQUIRED BY 21 CFR, 801.109)

510(k) Number: K992919

Device Name: Oxy Glide™ Root Canal Cleanser and Lubricant

Indications for Use:

Used in the chemical and mechanical cleansing of the root canal preparation during endodontic therapy

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992919