K102133

SYBRON DENTAL SPECIALTIES

OCT - 7 2010

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
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Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: July 2010

Device Name:

- Trade Name – *Giraffe2*
- Common Name – Gingival Retraction/Hemostatic Paste
- Classification Name – Unclassified

Device for Which Substantial Equivalence is Claimed:

- *Expa-syl,* Produits Dentaires Pierre Rolland

Device Description:

Giraffe2 is a paste containing a hemostatic agent which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam. *Giraffe2* is a tissue management solution that allows clinicians to quickly and easily obtain sulcular expansion in clinical situations prior to an impression. Additionally, *Giraffe2* will help stop bleeding and prevent the flow of crevicular fluid upon removal, further assuring accurate and complete impressions.

Intended Use of the Device:

Giraffe2 is a paste containing a hemostatic agent which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Substantial Equivalence:
Giraffe2 is substantially equivalent to another legally marketed device in the United States. *Giraffe2* functions in a manner similar to and is intended for the same use as *Expa-syl*, which is currently marketed by Kerr Corporation.

Giraffe2 contains the same hemostatic agent contained in *Expa-syl*. The difference between the *Giraffe2* and *Expa-syl* is the method of removal: *Giraffe2* is light cured allowing for easier removal, whereas Expa-syl needs to be rinsed thoroughly with water in order to be removed from the tooth.

Biocompatibility studies have been completed on *Giraffe2*, which demonstrate that the material is safe for its intended use. This 510(k) submission also includes data from bench testing used to evaluate the physical properties of *Giraffe2* compared to the predicate device, *Expa-syl*.

Based upon the biocompatibility and bench testing, the clinical performance of *Giraffe2* is deemed to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

OCT - 7 2010

Re: K102133
Trade/Device Name: Giraffe2
Regulation Number: None
Regulation Name: Retraction Cord
Regulatory Class: Unclassified
Product Codes: MVL
Dated: July 26, 2010
Received: July 29, 2010

Dear Ms. Garman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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

OCT - 7 2010

510(k) Number (if known): K102133

Device Name: *Giraffe2*

Indications For Use:

Giraffe2 is a paste containing a hemostatic agent which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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