K082116

""EXHIBIT "E"

Section III - SMDA Summary of Safety and effectiveness – "510(K) Summary"

1. Submitter Information:

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DEC 17 2008

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Date summary prepared: June 30th, 2008

2. Device name

Trade Name: **HEMOSTASYL Paste**

Common/Usual Name: RECTRACTION CORD

Classification Name: Unclassified

3. Devices for which Substantial Equivalence is claimed:

- ***EXPASYL*** (PRODUITS DENTAIRES PIERRE ROLLAND) K050180 Dated : 11/02/2005

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4. Device description:

PRESENTATION :

Box containing 2 x 2g-syringes of paste and 40 application cannulas
1x 2 g-syringes of paste and 20 application cannulas
Refills: Box containing 2 x 2g-syringes of paste
Box containing 1x 2g-syringes of paste
Box containing 40 application cannulas
Box containing 20 application cannulas

PROPERTIES

HEMOSTASYL is an original paste presented in syringes. It is designed to be used as a haemostatic dressing through two mechanisms of action. One is mechanical: it is achieved due to the viscosity and adhesiveness of the paste (clogging effect); the other is due to astringent properties of the aluminium chloride, which result in contraction of tissues and blood vessels.

The main characteristics of HEMOSTASYL are as follows:

- thixotropic properties
- good adhesion to the gingival mucosa, without compression
- presence of aluminium chloride which reinforces its mechanical haemostatic effect
- easily removed by gentle water spray without resumption of bleeding
- painless method when HEMOSTASYL is used on a healthy periodontium.
- contact time: 2 minutes

(A Summary of Product Characteristics is presented in Appendix F).

5. Intended use of the Device

"Hemostasyl Paste achieves its hemostatic effect in the gingival sulcus by physical and mechanical means during dental procedures such as dental impressions, scaling, seating of temporary and permanent restorations, and placement of a rubber dam."

Description of all known modes of action

HEMOSTASYL combined two mechanism of action:

- One is achieved due to the viscosity and adhesiveness of the paste, which allows the hydrogel to have a clogging effect as soon as it is in contact with the bleeding site.
This mechanical action is due to the structural properties of the paste and particularly its thixotropy: the anhydrous colloidal silica contained in the paste creates inside the paste a network of physical bonding. These bondings are responsible of the viscosity and adhesiveness of the paste. They have the particularity to break under shearing (then the paste is fluid when applied through the cannula) and to re-bond when no strength is applied (after deposit on the mucosa the paste recovers its initial consistency). This phenomenom allows the paste to exert its dressing-mechanical action including adhesive properties: the paste adheres to the surface of the dental mucosa despite of the bleeding (if moderate) and acts as a barrier : the paste (hydrogel) covers the wound and stops the bleeding. The action is observed only if the bleeding is moderate if not, the blood flow is too strong and the paste flows with the blood.

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The other action of HEMOSTASYL observed on bleeding is due astringent properties of aluminium chloride, which causes the collagen fibers around capillaries to swell. The expansion of the collagen around the capillaries induces pressure on them which causes them to constrict. Aluminium chloride doesn't act on the formation of coagulum.
This action can't be the first one observed because a small contact time is necessary to allow the aluminium chloride contained in the paste to act contrary to the mechanical action which is immediate and begins with the setting in place of HEMOSTASYL
There is no pharmacological or therapeutic effect because the components do not interfere with the clot formation process (coagulation).

6. Substantial Equivalence:.

The HEMOSTASYL is substantially equivalent to other legally marketed devices in the United States: EXPASYL is intended for a similar use (local haemostatic during dental procedures).

This product is substantial equivalent in its function and similar to the intended use to:

- 1 Product marketed by KERR Corp. (manufactured by: PRODUITS DENTIARES PIERRE ROLLAND): EXPASYL

Refer to Section IV for more detailed information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

SATELEC
C/O Mr. Rick Rosati
Quality Manager
ACTEON, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

Re: K082116
Trade/Device Name: HEMOSTASYL Paste
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: None
Product Code: MVL
Dated: December 4, 2008
Received: December 5, 2008

Dear Mr. Rosati:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082116

Exhibit "A"

Indication for Use

510(k) Number (if known): K082116

Device Name: **HEMOSTASYL Paste**

Indications For Use: "Hemostasyl Paste achieves its hemostatic effect in the gingival sulcus by physical and mechanical means during dental procedures such as dental impressions, scaling, seating of temporary and permanent restorations, and placement of a rubber dam."

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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