MAY 27 2005

K050658

510(k) Summary

Submitted by: Daniel J. Manelli
Manelli, Denison & Selter, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036

Telephone: 202-261-1000

On behalf of Hager Worldwide, Inc.
510(k) Submission: Reso-Pac
April 28, 2005

The product is a periodontal wound dressing. It is intended for use only by dental practitioners; and will not be offered for OTC use. It contains materials that pose no health hazard when used according to directions. Reso Pac has received approval for marketing in the European Community. It is substantially equivalent to other periodontal dressings, including PCA Periocare Periodontal Dressing (Pulpdent Corp. - K810545), Coe Pak (Coe Laboratories - K881422) and Barricaid (Dentsply International - K864720), which are intended to protect injured periodontal tissue by forming a temporary physical barrier to avoid further irritation.

Reso Pac should not be used with patients who are allergic to petrolatum products or oil derivatives.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2005

Hager Worldwide, Incorporated
C/O Mr. Daniel J. Manelli
Manelli Denison & Selter PLLC
2000 M. Street N.W. 7th Floor
Washington, DC 20036-3307

Re: K050658
Trade/Device Name: Hager Reso Pac Periodontal Dressing
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 11, 2005
Received: March 15, 2005

Dear Mr. Manelli:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Hager Reso Pac Periodontal Dressing

Indications for use:

For use as a periodontal wound dressing to protect injured periodontal tissue by forming a barrier to avoid further irritation.

(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

510(k) Number: K050658

Prescription Use √ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)