

K973440

510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:

Name: REXAM Medical Packaging
Address: 1919 S. Butterfield Road
Mundelein, IL 60060-9735
Contact Person: Denis G. Dyke
V.P., Quality and Regulatory Affairs
Phone Number: (847) 918-4606
FAX Number: (847) 362-1848
Date Prepared: September 9, 1997

Device Information:

Trade Name: REXAM Fracture Resistant Pouch
Common Name: Sterilization Pouch with or without Chemical
Sterilization Process Indicator
Classification: Sterilization Wrap, Chemical Sterilization Process
Name: Indicator

Predicate Device:

Trade Name: Registered trademark of REXAM Medical Packaging:
REXAM INTEGRA® Pack and OptiPeel®
Registered trademark of Allegiance Healthcare Corp.:
DualPeel®
Manufacturer: REXAM Medical Packaging

Device Description:

The predicate device and the REXAM Fracture Resistant Pouch are constructed of sterilizable kraft paper sealed to the polypropylene surface of a polyester-polypropylene plastic film lamination. Three sides

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of the pouch are sealed during manufacture. There are two versions of the REXAM Fracture Resistant Pouch: (1) a final heat seal closure of the paper and plastic film laminate components, and (2) a final self-seal closure employing a pressure sensitive self-seal tape assembled on the paper component and sealed to the polyester layer of the plastic film laminate. Both types of final closures are applied by the health care provider.

A chemical sterilization process indicator for steam or ethylene oxide sterilization, or both, may be incorporated to monitor exposure to the sterilant.

Intended Use:

The REXAM Fracture Resistant Pouch is a device intended to be used to enclose another medical device that is to be steam or ethylene oxide sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until its use.

The chemical process indicator on the REXAM Fracture Resistant Pouch is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process. The adequacy of the sterilization of the sterilization conditions as measures by these parameters is indicated by a visible change in the device.

Comparison of Technological Characteristics:

Sterilization pouches for gaseous-type sterilization are typically composed of a porous microbial barrier such as paper and a transparent, plastic film laminate. The plastic film laminate is typically composed of a polyester film component adhesively laminated to a polypropylene film component.

The REXAM Fracture Resistant Pouch has the same intended use as the

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predicate sterilization pouch but differs technologically through the use of a new polypropylene film component in the plastic film laminate. This improved component reduces fracture resistance upon pouch peel-open. All other components as well as the sterilization pouch and plastic film laminate method of manufacture are identical.

The performance of the REXAM Fracture Resistant Pouch was measured by film properties, seal strength, and film fracture rate pre-sterilization and post-sterilization, 270°F pre-vacuum steam and 100% ethylene oxide. All analyses were performed at a 95% confidence level, and the results illustrate equivalent plastic film laminate tensile and puncture properties, and sterilization pouch seal strengths. The REXAM Fracture Resistant Pouch differs technologically from the predicate sterilization pouch by providing a minimum of a 10 fold reduction in plastic film laminate fracture during peel-open. Through U.S. Pharmacopeia Agar Diffusion and Elution Testing, the plastic film lamination is proven to be safe.

The polypropylene film component change within the plastic film laminate produces a substantially equivalent sterilization pouch with a technological improvement in film fracture resistance upon opening that is safe and effective.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 20 1997

Ms. Andrea Haferkamp
Quality and Regulatory Manager
Rexam Medical Packaging
1919 South Butterfield Road
Mundelein, Illinois 60060-9735

Re: K973440
Trade Name: Rexam Fracture Resistant Pouch
Regulatory Class: II
Product Code: KCT
Dated: September 9, 1997
Received: September 10, 1997

Dear Ms. Haferkamp:

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.

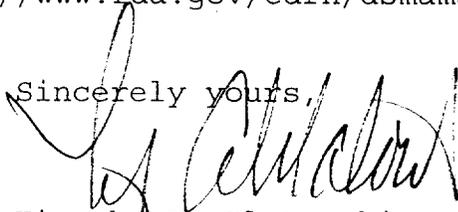
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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

510(k) Number (if known): _____

Device Name: REXAM Fracture Resistant Pouch

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of **Dental, Infection Control,**
and **General Hospital Devices**
510(k) Number K973440

Prescription Use _____ OR Over-The-Counter-Use X