

REXAM

K962600

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510(k) Summary

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

The assigned 510(k) number is: K962600

Applicant Information:

Date Prepared: August 5, 1996
Name: Rexam Medical Packaging
Address: 1919 S. Butterfield Road
Mundelein, IL 60060-9735
Contact Person: Quality and Regulatory Manager
Phone Number: (847) 362-9000
Fax Number: (847) 918-4660

Device Information:

Trade Name: Rexam Self-Seal Tyvek¹ Pouch
Common Name: Self-Seal Tyvek®/Film Sterilization Pouch
with or without Chemical Sterilization Process Indicator
Classification Name: Sterilization Wrap, Chemical Sterilization Process Indicator

Predicate Device:

Trade Name: Medi-Oxide™ Pouch
Manufacturer: Cur*Med, Curwood, Inc., a Bemis Company

Device Description:

The Rexam Self-Seal Tyvek® Pouch is constructed of medical grade Tyvek® sealed to polyethylene/polyester film. A chemical sterilization process indicator may be incorporated to monitor one or more of the sterilization process parameters. The final seal of the pouch is applied by the health care provider using the pressure sensitive self-seal tape closure. The self-seal tape closure facilitates manual sealing as an alternate method to heat sealing.

¹Tyvek is a registered trademark of E.I. duPont de Nemours & Company.

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Intended Use:

The Rexam Self-Seal Tyvek® Pouch is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider using a sterilization process where a non-cellulose pouch is indicated. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The chemical process indicator on the Rexam Self-Seal Tyvek® 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 conditions as measured by these parameters is indicated by a visible change in the device.

Comparison of Technological Characteristics:

The Rexam Self-Seal Tyvek® Pouch and the Medi-Oxide™ Pouch are both constructed of medical grade Tyvek® sealed to polyethylene/polyester film. The pressure sensitive tape closure on the Rexam Self-Seal Tyvek® Pouch and the Medi-Oxide™ Pouch are both one inch in width, and the seal is applied by the customer in the same manner for both products. The Medi-Oxide™ Pouch is manufactured without a chemical sterilization process indicator, and the Rexam Self-Seal Tyvek® Pouch may be manufactured with or without a chemical sterilization process indicator.

The performance of the self-seal tape closure on the Rexam Self-Seal Tyvek® Pouch was measured by seal strength and seal integrity tests, and compared to the performance of the self-seal tape on the Medi-Oxide™ Pouch. The seal strength test results were statistically analyzed at a 95% confidence level, and the test results indicate that both products were significantly above the minimum seal strength limit. The Rexam Self-Seal Tyvek® Pouch performed as well as the Medi-Oxide™ Pouch on the seal integrity tests.

The information submitted includes data that demonstrates that the Rexam Self-Seal Tyvek® Pouch is as safe and effective as the legally marketed Medi-Oxide™ Pouch, and that there are no new issues raised of safety and efficacy.