FEB 1 1 1998

510(k) Summary of Safety and Effectiveness

K973827

Manufacturer:	**Kimberly-Clark Corporation** **1400 Holcomb Bridge Road** **Roswell, GA 30076**
Regulatory Affairs Contact:	**Larry R. Kludt** **Department of Product Safety** **Kimberly-Clark Corporation** **1400 Holcomb Bridge Road** **Roswell, GA 30076** **(770) 587-8303**
Summary Date:	**September 30, 1997**
Product Trade Name:	**Kimberly-Clark™ Self-Seal Pouch for Low Temperature Sterilization**
Common Name:	**Sterilization Pouch**
Classification:	**Pack, Sterilization Wrapper Bag & Accessories**
Predicate Device:	**Medi-Oxide Sterilization Pouch**
Description:	**The Kimberly-Clark Self-Seal Pouch is available in sizes to suit the health care provider (3.5 " x 8.5", 5.25" x 10.25", 5" x 15", 7.5" x 13.5", 12" x 15", 12" x 18" & 15.75" x 18"). The pouch has a Tyvek backing with a clear, polyolefin/polyester film laminate material as a front.**
Intended Use:	**The Kimberly-Clark Self-Seal Pouch for Low Temperature Sterilization is intended to be used to enclose another medical device that is to be sterilized by a health care provider and to maintain sterility of the enclosed device until needed. The sterilization pouch is intended for use with low temperature sterilization processes (hydrogen peroxide gas plasma/STERRAD® sterilization system, peracetic acid gas plasma/Plazlyte™ sterilization process or ethylene oxide).**

Technological Characteristics

Both the Medi-Oxide pouch and the Kimberly-Clark Self-Seal Pouch for Low Temperature Sterilization are composed of the same materials (a porous, Tyvek backing to allow the sterilant to penetrate into the package and a polyolefin/polyester film as a front to allow viewing of the pouch contents). Both products are intended for use with low temperature sterilization processes and are able to maintain the sterility of their contents once sterilized.

Summary of Testing

Test	Result
Sterilant Penetration (STERRAD, Plazlyte and EO)	No growth of indicator organism
Microbial Barrier Efficiency (STERRAD, Plazlyte and EO)	No growth of indicator organism
Event Related Sterility Maintenance (EO only)	Superior to 140 count cloth packages in maintaining sterility

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Larry R. Kludt
Manager Regulatory Affairs
Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

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Re: K973827
Trade Name: Kimberly-Clark™ Self-Seal Pouch for Low Temperature Sterilization
Regulatory Class: II
Product Code: KCT
Dated: December 19, 1997
Received: December 22, 1997

Dear Mr. Kludt:

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): K973827

Device Name: Kimberly-Clark™ Self Seal Pouch for Low Temperature Sterilization

Indications For Use:

The Kimberly-Clark™ Self-Seal Pouch for Low Temperature Sterilization is intended to be used to enclose another medical device that is to be sterilized by a health care provider and to maintain sterility of the enclosed device until needed. The sterilization pouch is intended for use with low temperature sterilization processes (hydrogen peroxide gas plasma/STERRAD® Sterilization System, peracetic acid gas plasma/Plazlyte™ Sterilization Process or ethylene oxide).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Qian S. Lim

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K973827

Prescription Use____ (Per 21 CFR 801.109) OR Over-The-Counter Use X

(Optional Format 1-2-96)