Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1-847-949-2639
WATS: 1-800-950-0128
Fax: 1-847-949-2643

OCT 28 1998

Lara N. Simmons
Director of Regulatory Affairs

K982693

510(k) SUMMARY

July 13, 1998

1. Submitters Information:
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Phone: 847-949-2639
Fax: 847-837-2787
Contact: Lara Simmons, Corporate Regulatory Affairs

2. Device Information:
   A. Trade Name: Medline Disposable Sterile Zoned Impervious Surgical Gowns
   B. Common Name: Sterile Disposable Surgeon's Gowns
   C. Classification Name: Surgical Gown
   D. Panel and ProCode: 79FYA Class II Device

3. Substantial Equivalence Claim:
Medline claims substantial equivalence to Johnson & Johnson Medical, Inc.'s Barrier Fabric 450 Surgical Gown, K934608.

4. Device Description:
Medline Disposable Sterile Zoned Impervious Surgical Gowns are manufactured from a non-woven fabric which is laminated to a plastic film. Because the plastic film is made of microporous polyethylene, it provides protection from inward liquid penetration as well as comfort by allowing outward passage of vapor. These products are disposable and intended for single use only.

The Sontara Spunlace Fabric is produced by DuPont. It is a hydroentangled (or hydrolaced) fabric made using a Spunlace technology. For medical applications, the content is approximately 55% wood pulp and 45% polyester. The interlaced fibers and surface finish give Sontara outstanding barrier properties while providing the comfort features of re-usable linens.

This product has seams which are bound to provide strength and barrier properties. Tape is utilized to cover the drill holes required during manufacturing. There are long stockinet cuffs on the sleeves for added comfort and protection. Both Velcro and snaps are offered as closures. The materials used in Medline's gowns are strong, do not unravel or delaminate and are low in lint.

5. Intended Use:
Medline Disposable Sterile Zoned Impervious Surgical Gowns are surgical apparel that is intended to be worn by operating room personnel during surgical procedures to protect

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both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

6. Technological Characteristics:
There are no technological differences between the new device and the predicate device. They are both made from material that is functionally the same.

7. Non-Clinical Performance Data:

Feature	**Medline**	**Predicate**
Material Composition	Sontara Spunlace – a Non-Woven hydroentangled (or hydrolaced) fabric made using a Spunlace Technology	Johnson & Johnson Fabric 450 is a non-woven hydroentangled fabric made using a spunlace technology
Weight Per Square Yard	1.70 oz/yd^2	2.1 oz/yd^2
Thickness	9.4 mils	10.0 mils

The safety and effectiveness of Medline Disposable Sterile Zoned Impervious Surgical Gowns are dependent upon proper usage of the product. When used per the instructions, these products provide a barrier to help prevent contamination of the otherwise sterile fields during medical and surgical procedures and provide a protective barrier to help prevent the migration of blood-borne pathogens.

8. Viral Penetration and Synthetic Blood Penetration Studies.
Medline Industries, Inc. Zoned Impervious Surgical Gowns have been tested under both ASTM F1670 (Synthetic Blood Penetration) and ASTM F1671 (Viral Penetration).

9. Biocompatibility
These devices meet the requirements for biocompatibility per ISO10993 for surface devices, intact skin, limited duration (<24 hours).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Ms. Lara Simmons
Corporate Regulatory Affairs
Medline Industries, Incorporated
One Medline Place
Mundelein, Illinois 60060

Re: K982693
Trade Name: Medline Disposable Sterile, Surgical Gowns Zoned Impervious
Regulatory Class: II
Product Code: FYA
Dated: July 13, 1998
Received: August 3, 1998

Dear Ms. Simmons:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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

INTENDED USE

510(k) Number (if known): (N/A)

Device Name: Medline Disposable Sterile Surgical Gowns, Zoned Impervious

Indications for Use:

Medline Disposable Sterile Surgical Gowns, Zoned Impervious are surgical apparel that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982693

(Optional Format 1-2-96)