

4/13/99

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS
for the new BARRIER* surgical gowns

Johnson & Johnson Medical™
Division of Ethicon Inc.
2500 Arbrook Boulevard
P.O. Box 90130
Arlington, Texas 76004-3130

K990395

Date:

1. Submitter Information:

Contact Person: Jane Ann Martin
Phone: 817-262-4048
Fax: 817-262-5369

2. Device Name:

Trade Name: BARRIER* surgical gowns
Common/Usual Name: surgical gown
Classification Name: surgical gown
Device Classification: Class II, 21CFR878.4040

3. Statement of Substantial Equivalence:

BARRIER surgical gowns with the new non-wovens are substantially equivalent to the BARRIER Extra Protection Plus surgical gown.

4. Intended Use:

A BARRIER surgical gown is a single use article of surgical apparel 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.

5. Device Description:

The new BARRIER surgical gowns have high repellency areas (front and lower sleeves) constructed from new breathable repellent materials.

6. Material Safety Testing Summary

The new materials meet ISO 10993-1 requirements for material safety and biocompatibility.

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7. Performance Testing Summary:

The new materials were tested versus the predicate materials in the applicable standard material evaluations as indicated in the October, 1993, FDA 510(k) Surgical Gown guidance document. The new materials have higher breathability with equivalent strength and repellency as compared to the predicate's. The new gowns meet the Class I flammability requirements of 16CFR1610 and pass the ASTM Standard Test Method 1671, Resistance of Protective Clothing Materials to Penetration by Bloodborne Pathogens Using Viral Penetration as a Test System. The new fabrics are also lighter in weight than the predicate materials, resulting in lower disposal costs where disposal cost is based on weight. The high repellency zones of the new gowns are also larger in area dimensionally than the reinforced zones in the predicate gown.

8. Conclusion:

The new BARRIER surgical gowns are safe and effective for their intended use and are substantially equivalent to the predicate device.

* TRADEMARK



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 1999

Ms. Jane Ann Martin
Johnson & Johnson Medical™
Division of Ethicon, Incorporated
2500 Arbrook Boulevard
P.O. Box 90130
Arlington, Texas 76004-3130

Re: K990395
Trade Name: BARRIER Surgical Gowns (Six) Sterile and
Non-Sterile Disposable
Regulatory Class: II
Product Code: FYA
Dated: February 5, 1999
Received: February 9, 1999

Dear Ms. Martin

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 (Pre-market 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

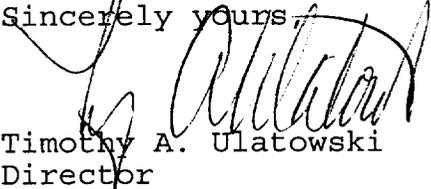
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

Indications for Use Statement

Applicant: Johnson & Johnson Medical, Division of Ethicon, Inc.

510(k) Number (if known): K990395

Device Name:

BARRIER* Surgical Gowns (6), sterile and Non-sterile, Disposable

Indications For Use:

A BARRIER surgical gown is a single use article of surgical apparel 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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)

OR Over-the-Counter Use: X

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K990395

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