JAN 14 1999

XVI. 510 (k) Summary K982058

Manufacturer:	Dowling Textile Company 615 Macon Road McDonough, Georgia 30253 (770) 957-3981
Regulatory Contact:	Tim Cummins
Common Name:	Reusable Surgical Gown
Trade Name:	Rotecno® FR Surgical Gown
Classification Number:	79FYA
Class, Regulation:	II per 21 CFR §878.4040
Predicate Device:	SafeCare™ Reusable Surgical Gown
Device Description:	A reusable surgical gown fabricated from 99% polyester, 1% carbon, chemically treated fabric and designed to provide fluid protection through up to 150 laundry/sterilization cycles.
Intended Use:	"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."
Substantial Equivalence:	The Rotecno® FR Surgical Gown is substantially equivalent to the SafeCare™ Gown in material, design, form, fit, and function.
Toxicity Testing Summary:	The material used in the fabrication of the Rotecno® FR Surgical Gown has been found acceptable for its intended use.
Performance Testing Summary:	The Rotecno® FR Surgical Gown has been tested for breaking strength, tear resistance, air permeability, water repellency, impact penetration, hydrostatic head, flammability, and aqueous bacterial barrier and found acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Mr. Tim Cummins
RA/QA Manager
Dowling Textile Company
P.O. Box 598
615 Macon Road
McDonough, Georgia 30253

Re: K982058
Trade Name: Rotecno® FR (Fluid Resistant) Surgical Gown
Regulatory Class: II
Product Code: FYA
Dated: December 14, 1998
Received: December 21, 1998

Dear Mr. Cummins:

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 legally marketed predicate 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/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): K982058

Device Name: Rotecno® FR Surgical Gown, Non-sterile and Reusable

Indications For Use:

"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)

George I. Mills for Chiu S. Lin, PhD

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982058

Prescription Use_______ OR Over-The-Counter Use ✓

(Optional Format 1-2-96)