

NOV 20 2003

DeRoyal Industries, Inc.

K033057

DeRoyal Surgical Gowns

510(k) Summary

Summary of the Safety and Effectiveness Information
Upon Which
An Equivalence Determination Could Be Based

SUBMITTER INFORMATION:

| | | | |
|-----------------|--------------------------|-----------------------------|--------------------|
| NAME: | DeRoyal Industries, Inc. | TELEPHONE: | (865) 362-6157 |
| ADDRESS: | 200 DeBusk Lane | CONTACT: | Sharon Cook |
| | Powell, TN 37849 | DATE OF PREPARATION: | September 25, 2003 |

DEVICE NAMES

Name: Surgical Gowns
COMMON/USUAL NAME: Surgical Gowns
CLASSIFICATION NAME: FYA, Surgical Apparel
Class II device, per 878.4040

PREDICATE OR LEGALLY MARKETED DEVICES

PrimeLine primaGARD Surgical Gowns (K023117)
Precept Ultraguard™ Surgical Gowns (no 510k available, Owner/Operator number 9038820)

DEVICE DESCRIPTION

The DeRoyal Surgical Gowns are comprised of Polypropylene Spunbond Meltblown Spunbond (SMS) material commonly used in the industry for these devices. The devices have been tested according to relevant performance standards (ISO 10993, AATCC 127, AATCC42, ASTM1671, 16 CFR 1610, ASTM 1342, ASTM D1424, ASTM D5034, NFPA Standards) to determine their equivalency to the predicate devices.

DEVICE INTENDED USE

The DeRoyal Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect both the operating room personnel and the patient from the transfer of microorganisms, body fluids and other particulate material.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETED DEVICES

| Characteristic | DeRoyal Device | Other Devices |
|----------------|---|---|
| Material | Spunbond Meltblown Spunbond (SMS) | Spunbond Meltblown Spunbond (SMS) |
| Color | Blue | Blue |
| Sizes | Various | Various |
| Sterility | Sterile and Non-Sterile | Sterile and Non-Sterile |
| Disposable | Yes | Yes |
| Package | Bulk, single put-ups or as a component in trays or kits | Bulk, single put ups or as a component in trays or kits |



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon Cook
Regulatory Affairs Group Manager
DeRoyal Industries, Incorporated
200 DeBusk Lane
Powell, Tennessee 37849

Re: K033057

Trade/Device Name: DeRoyal Surgical Gowns, Sterile, Non-Sterile
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: September 25, 2003
Received: September 29, 2003

Dear Ms. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



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Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k): K033057

Device Name: DeRoyal Surgical Gowns, sterile, non-sterile

Intended Use: DeRoyal Surgical Gowns are identified in 21 CFR, part 878.4040 as surgical attire to be worn by operating room personnel during surgical procedures to protect both operating room personnel and the patient from the transfer of microorganisms, body fluids and other particulate materials.

Sisanna F. Parulo

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033057

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)