

MAY 15 1998

K980210

510(k) SUMMARY

Submitted by: DEKA Medical, Inc.
4820 Executive Park Court, Suite 110
Jacksonville, FL 32216

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Contact: Donald G. White

Prepared: 20 January 1998 (Original Submission)
28 April 1998 (revised)

Proprietary Name: Patient Drape

Common Name: Surgical Drape or Patient Drape

Classification Name: Drape, Surgical (21 CFR Part 878.4370)

Predicate Device: Invotec International, Inc. Ear Drape
(K911039)

Device Description: DEKA Medical, Inc., will market Surgical Drapes composed of nonwoven fabric or polyethylene film and are of various configurations appropriate for Otological, Ophthalmic, Heart & Neurological, Peri/OB, Arthroscopic, and Specialty Procedures. These devices use nonwoven and film materials as a protective patient covering during surgical procedures. These barrier materials are essentially impervious to fluid transfer across them, thus function to isolate the operative site from the surrounding area. Drapes may feature tape adhesive to temporarily bind the drape to the periphery of the operative site. Fluid collection pouches are attached to the drape for collection of operative wound solid and liquid effluents. The DEKA Medical Surgical Drapes will be subjected to a sterilizing dose of gamma radiation sufficient to achieve a Sterility Assurance Level (SAL) of 10^{-6} .

Intended Use: The various surgical or patient drapes manufactured by DEKA Medical, Inc., consist of natural or synthetic materials intended to be used as a protective patient covering during Otological, Ophthalmic, Heart & Neurological, Peri/OB, Arthroscopic, and Specialty Procedures. The primary purpose of the drapes is to isolate a site of surgical incision from microbial or other contamination. The target population for both the Invotec Ear Drape and the DEKA Medical Surgical Drapes is patients undergoing Otological procedures. In addition the DEKA Medical Surgical

Drapes are intended for patients undergoing Ophthalmic, Heart & Neurological, Peri/OB, Arthroscopic, and Specialty Procedures. Substantial equivalence is evidenced by the fact that both the Invotec Ear Drape and the DEKA Medical Surgical Drapes are constructed of nonwoven fabric or polyethylene film. Data provided by suppliers of these materials for the DEKA Medical Surgical Drapes indicate they are impermeable to fluids and are compatible for skin contact applications.

The primary difference between the Invotec Ear Drape and the DEKA Medical Surgical Drapes is the method of sterilization. The Invotec Ear Drape is Ethylene Oxide sterilized whereas the DEKA Medical Surgical Drapes are gamma irradiation sterilized. However, sterility is assured by either method and the DEKA Medical Surgical drapes have been found to be biocompatible following gamma irradiation.

Technological Comparison: A comparison of the technological characteristics of the DEKA Medical, Inc., surgical drape and the Invotec ear drape is indicated in the table below:

Characteristic	Invotec Ear Drape	DEKA Surgical Drapes
Indications for use	Otological Procedures	Otological, Ophthalmic, Heart & Neurological, OB/GYN, and Arthroscopic Procedures
Target Population	Otological Surgery candidates	Candidates for Otological, Ophthalmic, Heart & Neurological, Peri/OB, and Arthroscopic Procedures
Design	Isolates ear surgical site from surrounding area through the use of barrier materials	Isolates ear, eye, chest, abdomen, pelvic, or extremities from surrounding area depending on drape through the use of barrier materials. Incorporates fluid collection attachments depending on drape.
Materials	Polyethylene film or nonwoven fabrics	Nonwoven fabrics, Polyethylene film,

Characteristic	Invotec Ear Drape	DEKA Surgical Drapes
	adhesive tapes	adhesive tapes
Performance	See adjoining table	See adjoining table
Sterility	Per ISO 11135	Per ISO 11137
Biocompatibility	Skin contact only	None irritating or sensitizing to ISO 10993-10 Standard

Nonclinical Test Data

Physical properties data was obtained from suppliers of DEKA Medical Surgical Drape nonwoven fabric, polyethylene films, and skin contacting adhesives. These data show the Dexter nonwoven fabric and the various thickness of polyethylene film are impermeable to liquids for the duration of the indicated procedures (see Table below). Tensile strength and puncture resistance data indicate these materials have sufficient tensile strength and puncture resistance to maintain barrier integrity during indicated procedures. The DEKA Medical nonwoven fabric and foam laminate pass the 16 CFR Part 1610 Flammability Classification (Flammability Class 1 and 2). No Classification data is available on DEKA Medical Surgical Drape polyethylene film. However, the flammability of various polyethylene films is comparable and would not be substantially different in flammability from the Invotec Ear Drape polyethylene film. Biocompatibility testing in conformance to ISO 10993-10 of a gamma sterilized Composite Patient Drape shows the drapes to be nonirritating and nonsensitizing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald G. White
Director QA/RA
Deka™ Medical, Incorporated
4820 Executive Park Court, Suite 110
Jacksonville, Florida 32216

Re: K980210
Trade Name: Various Surgical or Patient Drapes
Regulatory Class: II
Product Code: KKK
Dated: April 29, 1998
Received: April 30, 1998

Dear Mr. White:

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

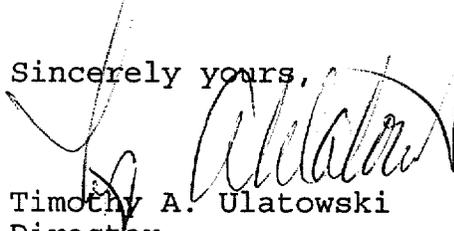
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): K980210

Device Name: Various Surgical or Patient Drapes

STATEMENT OF INDICATIONS FOR USE

The various surgical or patient drapes manufactured by DEKA Medical, Inc., consist of natural or synthetic materials intended to be used as a protective patient covering during surgical procedures. The primary purpose of the drapes is to isolate a site of surgical incision from microbial or other contamination.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chun S. Lin

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

510(k) Number K980210

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)