OCT 20 1997

PROTEK MEDICAL PRODUCTS INC.
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October 17, 1997

Document Mail Center
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

SUMMARY
PREMARKET NOTIFICATION 510 (k)
FOR
POLYETHYLENE ULTRASOUND TRANSDUCER SURGICAL DRAPE KIT

SUBMITTER:	Rick L. Pruter
COMPANY:	PROTEK Medical Products Inc.
ADDRESS:	221 East Market Street
CITY:	Iowa City
STATE:	Iowa
COUNTRY:	USA
CONTACT:	Rick L. Pruter
PHONE:	(319)358-8080
FAX:	(319)339-8258
DATE SUMMARY PREPARED:	January 21, 1997
TRADE NAME:	ULTRASOUND TRANSDUCER DRAPE KIT - POLYETHYLENE
COMMON NAME:	TRANSDUCER COVER, PROBE COVER, SURGICAL DRAPE, INSTRUMENT COVER
CLASSIFICATION NAME:	SURGICAL DRAPE (per 21 CFR Section 878.4370)

SUMMARY

COMMERCIALLY PRODUCED PRODUCTS OF EQUIVALENCE:

There are several products of equivalence legally marketed including the following: Amedic of Sweden, MicroTek of Mississippi, USA and Civco Medical from Iowa, USA.

These devices are similar to the predicate devices in respect to the materials, packaging, distribution and intended use.

Substantial Equivalence Comparison:

The following is a cross reference of products that will be identical:

New Device	Predicate Device	
PROTEK Medical Inc.	***Civco***	***Civco's 510(k)***
1-519-0122	610-013	K844472
1-519-0124	610-015	K844472
1-519-0126	610-209	K844472

*Other part numbers vary only on size and shape

These new products have the same intended use as legally marketed devices. The same end users. The same material manufactures the same tests and processes as Civco's legally marketed devices under 510(k) K844472.

SUMMARY

DEVICE DESCRIPTION:

Narrative Description:

A variety of kits, ranging in sizes, containing a disposable, single use, sterile instrument cover/drape, gel, bands and tape. The sterile bag is placed over a non-sterile ultrasound transducer probe during a sterile procedure, acting as a barrier between the patient and the ultrasound probe.

Device Physical Specifications:

Each kit contains one cover/drape, ranging in sizes from 2"x24" to 5"x100", made from extruded Polyethylene film, with a thickness of .001inches-.003inches, Conductivity Gel, Elastic Bands, and Plastic Medical Tape.

Intended use:

A polyethylene cover/drape kit used as an accessory to an ultrasound transducer. The sterile cover/drape acts as a barrier as is placed on the instrument prior to coming in contact with the human bodies internal and external services. The following is an abbreviated list of known uses:

1. General Purpose: Ultrasound scanning.
2. Cord cover for an extended sterile field on ultrasound transducer cords.
3. Rectal and vaginal scanning.
4. Drapes on Ultrasound Transducers used as protective coverings to isolate a site of surgical incisions from microbial and other contamination.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

(SEE ATTACHED CHART - APPENDIX D)

Appendix D in SUMMARY

Substantially Equivalence Comparison Chart With Civco Medical K844472

Description	PROTEK Medical Products Inc.	Civco Medical
Indications for use	Ultrasound transducer covers	Ultrasound transducer covers
Target Population	Sonographers, Doctor's and Technicians	Sonographers, Doctor's and Technicians
Design	Sizes & Shapes Varies	Sizes & Shapes Varies
Materials	Polyethylene .001-.003inches	Polyethylene .001-.003inches
Additional Kit Components	Conductivity Gel Elastic Bands Plastic Medical Tape	Conductivity Gel Elastic Bands
Performance	ASTM - F1671-95	ASTM - F1671-95
Sterility	ETO	ETO
Biocompatibility	ISO-10993	ISO-10993
Mechanical Safety	Tensile Strength 2400 - 3500 PSI	Tensile Strength 2400 - 3500 PSI
Chemical Safety	No Hazardous Components 29CFR 1910.1200	No Hazardous Components 29CFR 1910.1200
Anatomical Sites	Where Ultrasound is Used	Where Ultrasound is Used
Disposition	Disposable	Disposable
Where Used	Hospitals & Clinics	Hospitals & Clinics
Standards Met	Global Test Methods for Resistance to Penetration	Global Test Methods for Resistance to Penetration
Electrical Safety	No Electrical Components	No Electrical Components
Manufacturing Method	Vertrod Heat Sealer	Vertrod Heat Sealer
Packaging	TYVEK "Chevron Peel Pouch"	TYVEK "Chevron Peel Pouch"
Human Factor	No Known Adverse Effects	No Known Adverse Effects

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Rick L. Pruter
President/CEO
PROTEK Medical Products Incorporated
221 E. Market Street, Suite 291
Iowa City, Iowa 52245

OCT 20 1997

Re: K970889
Trade Name: Ultrasound Transducer Drape Kits, Polyurethane
Regulatory Class: II
Product Code: KKX
Dated: July 1, 1997
Received: July 23, 1997

Dear Mr. Pruter:

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 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

In addition, we have determined that your device kit contains Ultra/Phonic Conductivity Gel which are subject to regulation as drug.

Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component[s]. For information on applicable Agency requirements for marketing this [these] drug[s], we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

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 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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 "dsmo@fdadr.cdrh.fda.gov".

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

510(k) Number K970889

Statement
Indication For Use

Device Name: Polyethylene Ultrasound Transducer Drape: Kit

I, Rick L. Pruter, President/CEO of PROTEK Medical Products Inc., certify that the devices in this notification are used for:

Drapes on Ultrasound Transducers used as protective coverings to isolate a site of surgical incisions from microbial and other contaminations.

Rick L. Pruter, President/CEO
PROTEK Medical Products Inc.

July 16, 97
Date

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K970889