



OCT 26 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rick L. Pruter
PROTEK Medical Products, Incorporated
221 East Market Street, Suite 291
Iowa City, Iowa 52245-2166

Re: K970891

Trade/Device Name: Latex Ultrasound Transducer Surgical Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KXX
Dated: July 12, 1997
Received: July 23, 1997

Dear Mr. Pruter:

This letter corrects our substantially equivalent letter of August 22, 1997 regarding the product code.

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 (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 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.

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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 continue 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 (240) 276-0115. 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,



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

K970891



**PROTEK
MEDICAL PRODUCTS INC.**

211 E. MARKET SUITE 291 IOWA CITY IA
319-358-8080 FAX 319-339-8258
USA 52245-2166

AUG 22 1997

February 20, 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
LATEX
ULTRASOUND TRANSDUCER SURGICAL DRAPE**

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-LATEX
COMMON NAME: TRANSDUCER COVER, PROBE COVER,
SURGICAL DRAPE, INSTRUMENT COVER

CLASSIFICATION NAME: SURGICAL DRAPE (per 21 CFR Section 878.4370)

SUMMARY

COMMERCIALY 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, (details in body of this submission appendix).

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 Products Inc.		Civco's	Civco's 510(k)
1-519-0350	5 X 30	610-043	K895614
1-519-0380	8 X 30	610-044	K895614
1-519-0399	10 X 30	610-046	K895614
1-519-0320	2 X 20	610-075	K895614
1-519-0326	2.6 X 20	610-213	K895614
1-519-0335	3.5 X 20	610-214	K895614
1-519-0336	3.5 X 20	610-010	K895614

*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 and the same people that tested and processed Civco's legally marketed devices. Other 510(k) numbers that have the same intended use are K844472 and K943393 under Civco Medical, K882724 MicroTek Probe Drape and 3m #1071 Drape

SUMMARY

DEVICE DESCRIPTION:

Narrative Description:

A sterile bag to contain a non-sterile ultrasound transducer probe during a sterile procedure.

A disposable, single use, sterile instrument cover/drape to protect the patients from cross contamination from bacteria's of a non-sterile ultrasound transducer probe.

A sterile barrier between patient and ultrasound transducer probe.

Device Physical Specifications:

Dip molded natural latex rubber

Thickness-.001-.007

Sizes-Sizes range from 1.5cm X 10cm thru 8.0cm x 30cm

Intended use:

A cover/drape or sterile barrier placed on an ultrasound transducer 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. Intro-operative procedure that use non-sterile ultrasound transducers and require an extra sterile barrier. This would include invasive procedures where blood path indirect contact may occur.
3. Rectal and vaginal scanning.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

(SEE ATTACHED CHART - APPENDIX D)

Appendix D in SUMMARY**Substantially Equivalence Comparison Chart With Civco Medical**

Description Comment	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	LATEX.001-.007	LATEX .001-.007
Vendors	Kent Latex, Ohio Killian Latex, Ohio	Kent Latex, Ohio Killian Latex, Ohio
Performance	ASTM - ES - 22	ASTM - ES - 22
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
Manufacturing Method	Dipped Latex	Vertrod Heat Sealer
Packaging	TYVEK "Chevron Peel Pouch"	TYVEK "Chevron Peel Pouch"
Human Factor	Labels identify this product as Latex	Labels identify this product as Latex

