



OCT 20 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Leo Wei
Director, Quality Assurance/Regulatory Affairs
ProMEDICAL Product Company, Limited
206 Haung He Road West, New North District
Changzhou, Jiangsu
CHINA 213022

Re: K080629
Trade/Device Name: proMedical Surgical Drape
proMedical Surgical Equipment Cover
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KXX, MMP
Dated: September 24, 2008
Received: October 1, 2008

Dear Mr. Wei:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K080629

Devise name: proMedical Surgical Drape

Indications for use:

proMedical Products Co. LTD intends to market sterile surgical drapes identified in 21 CFR 878.4370 as device made of natural or synthetic material intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

Drape Model Family	Drape Name	Model Code	Drape Materials
Angiography Drape	Angiography Surgical Drape	19-001	SMS base panel with air-laid pad and polyethylene sides
Fenestrated Drape	Clear Legging Surgical Drape	19-020	Polyethylene panel
Extremity Drape	Universal Extremity Surgical Drape	19-051	SMS base panel with air-laid pad
	Legging Surgical Drape	19-052	SMS panel
	Head Surgical Drape	19-053	SMS panel
	Side Surgical Drape	19-054	SMS base panel with air-laid pad
	Top Surgical Drape	19-055	SMS base panel with air-laid pad
	Bottom Surgical Drape	19-056	SMS base panel with air-laid pad
	Bar Surgical Drape	19-057	SMS base panel with air-laid pad
Laparotomy Drape	Laparotomy Surgical Drape	19-100	Spunlace base panel with air-laid pad
Arthroscopy Drape	Arthroscopy Surgical Drape	19-151	SMS base panel with polyethylene pouch
Under buttocks Drape	Under buttocks Surgical Drape	19-201	SMS base panel with air-laid Pad and polyethylene pouch
Split Drapes	Split Surgical Drape	19-251	SMS base panel with air-laid pad
Lithotomy Drape	Lithotomy Surgical Drape	19-301	SMS base panel with air-laid pad
Laparoscopic Drape	Laparoscopic Surgical Drape	19-351	SMS base panel with air-laid pad
Thyroid Drape	Thyroid Surgical Drape	19-401	SMS base panel with air-laid pad
Abdominal Drape	Abdominal Surgical Drape	19-451	SMS panel

Drape Model Family	Drape Name	Model Code	Drape Materials
C-section Drape	C-section Surgical Drape	19-501	SMS base panel with polyethylene pouch
Minor Procedure Drape	Minor Procedure Surgical Drape	19-551	SMS base panel with air-laid pad
Lap Chole Drape	Lap Chole Surgical Drape	19-601	SMS base panel with air-laid pad
Universal Spine Drape	Universal Spine Surgical Drape	19-651	SMS base panel with air-laid pad
Cystoscopy T Surgical Drape	Cystoscopy T Surgical Drape	19-701	SMS base panel with air-laid pad
Chest Surgical Drape	Chest Surgical Drape	19-751	SMS base panel with air-laid pad
Utility Surgical Drape	Utility Surgical Drape	19-801	Air-laid absorbent panel
Ophthalmic Drape	Ophthalmic Surgical Drape	19-851	SMS base panel with polyethylene pouch
Cardiovascular Drape	Cardiovascular Surgical Drape	19-901	Air-laid absorbent panel with a polyethylene backing
Aperture Drape	Aperture Surgical Drape	19-951	Air-laid absorbent panel with a polyethylene backing

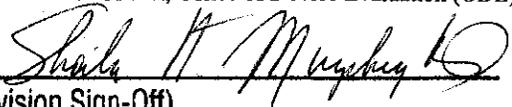
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 080629

Indications for Use

510(k) Number (if known): K080629

Devise name: proMedical Surgical Equipment Cover

Indications for use:

proMedical Products Co. LTD intends to market Sterile surgical equipment covers which are protective barrier covers that are intended to be used to cover surgical equipment and provide a protective barrier for that equipment.

Cover Name	Model Code	Cover Materials
Band Bag	14-001	Polyethylene bag
Mayo Stand Cover	15-001	Blue polyethylene tube with Air-laid reinforcement
Table Cover	16-001	Blue polyethylene film with Air-laid reinforcement



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080629

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

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