K042131

DEC 1 0 2004

510(k) Notification

SECTION A – GENERAL INFORMATION

Date:	August 3, 2004
Applicant's Name:	proMedical Products Co. LTD
Address:	#206 Huang He Road West Changzhou New District Changzhou, Jiangsu China 213022
Phone:	011-86-0519-5115027
Fax:	011-86-519-5115027
Contact Name/U.S Authorized Rep:	Mr. David Power 5165 Broadway #116 Depew, NY 14043-4012
Phone:	716-655-3432
Fax:	716-655-3432
Manufacturing Location:	proMedical Products Co. LTD #206 Huang He Road West Changzhou New District Changzhou, Jiangsu China 213022
Owner/Operator No.	9064470
Establishment Registration No.	N/A – awaiting assignment of number
Common Name of Device:	Non-sterile Disposable Surgical Drapes
Trade Name:	proMedical Surgical Drapes
Classification:	Class II
Product Code:	KKX
Regulation Number:	878.4370
Purpose of Submission:	New Device

K042'3

Predicate Device(s):	Primeline (Primaguard) surgical drapes (k021864) Medline (Proxima) surgical drapes (k964142)
510k Prepared by:	Boyd Harris 125 Clements Ave Starkville, MS 39759 662-312-0898 (Phone) 662-324-6347 (Fax) kotacan@hotmail.com (email)

*** Please refer all questions, request for additional information, and/or any correspondence regarding this 510(k) submission to Boyd Harris using the above contact information.**

Applicant's Signature:

David Power 8-1-04

Mr. David Power Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2004

Mr. Boyd Harris
Director, Quality Assurance/Regulatory Affairs
proMedical Products Company, Limited
125 Clements Avenue
Starkville, Mississippi 39759

Re: K042131
Trade/Device Name: Surgical Drapes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: October 15, 2004
Received: October 18, 2004

Dear Mr. Harris:

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.

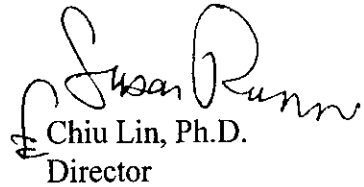
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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

Indications for Use

510k Number (if known): k042131

Device Name: Surgical Drapes

Indications For Use:

proMedical Products Co. LTD intends to market Non-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

Prescription Use X AND/OR Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzette M. Chan M.D.

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

510(k) Number K042131