



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Ms. Brenda Lee
Manager, Regulatory Affairs & Quality Assurance
PrimeLine Medical Products, Incorporated
10707-100th Avenue, Suite 300
Edmonton, Alberta
CANADA T5J 3M1

Re: K021864
Trade/Device Name: Primagard Nonsterile Femoral Angiography Drapes
(Models PM1-0136, PM1-0119, PM1-0142)
Regulation Number: 878.4370
Regulation Name: Surgical Draper and Drape Accessories
Regulatory Class: II
Product Code: KXX
Dated: September 10, 2002
Received: September 11, 2002

Dear Ms. Lee

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.

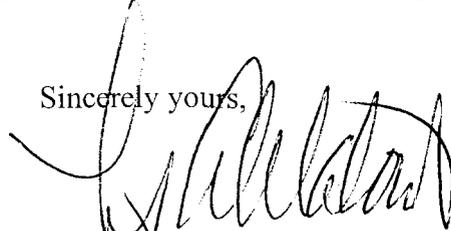
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K 021864

FEMORAL ANGIOGRAPHY

Device Name: PrimeLine Medical Products Inc. primaGARD Surgical Drapes

The primaGARD Surgical Drapes are NON Sterile Surgical Drape, identified in 21 CFR, part 878.4730, as a medical device intended to be used by operating room personnel during surgical procedures to protect both the surgical patients and the operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The drapes are made of natural and/or synthetic material and used as a protective patient covering. One example of use of this drape is to isolate the site of surgical incision from particulate, microbial and other forms of contamination.

Brenda

Brenda Lee

June 5, 2002

Date:

K021864

Premarket Notification (510K Number)

Chiu S. Lin

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

510(k) Number: K 021864