



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 16 2002

Ms. Brenda Lee  
Manager of RA/QA  
Primeline Medical Products, Incorporated  
10707-100<sup>th</sup> Avenue, Suite 300  
Edmonton, Alberta,  
CANADA T5J 3M1

Re: K021076

Trade/Device Name: Primagard Yellow Surgical Mask, Pleated, Tie-On, PM4-307  
Regulation Number: 878.4040  
Regulation Name: Surgical Mask  
Regulatory Class: II  
Product Code: FXX  
Dated: April 1, 2002  
Received: April 3, 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.

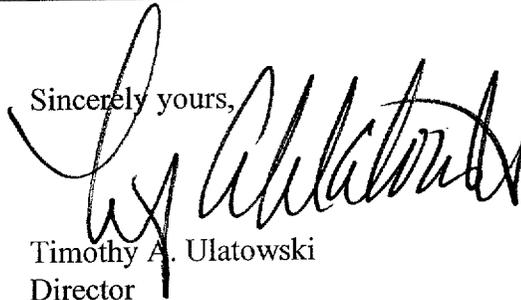
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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

Enclosure

**Statement of Indications for Use**

510(k) Number: K 021076

Device Name: PrimeLine Medical Products Inc. Yellow Surgical Mask  
PrimeLine Medical Products Inc. Anti-Fog Surgical Mask  
PrimeLine Medical Products Inc. Platypus Surgical Mask

Surgical Masks are surgical apparel, identified in 21 CFR, part 878.4040, as a medical device intended to be worn 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.

I certify that, in my capacity as Manager of Regulatory Affairs and Quality Assurance of PrimeLine Medical Products Inc., that the intended use of modified masks (PM4-307 and PM4-308, PM4-311, PM4-312, PM3-313) has not changed from the intended use of the marketed masks under the 510K number: K001951.



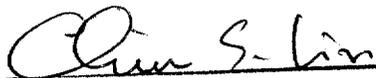
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Brenda Lee

April 1<sup>st</sup>, 2002

\_\_\_\_\_  
Date:

K021076

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Premarket Notification (510K Number)



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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K021076