K081633

510(k) Summary

Submitted by:	priMED Medical Products Inc. #900, 10707-100 Avenue Edmonton, Alberta T5J 3M1 Telephone: 780-497-7600
Contact Person:	Raymond G. Marusyk
Date Prepared:	June 10, 2008
Proprietary Name:	PRIMAGARD™ Surgical Mask
Common Name:	Surgical Mask
Classification Name:	Surgical Mask, 878.4040; Product Code FXX
Predicate Device:	Surgical Mask 510(k) #K001951

AUG 11 2008

Description of the Device: These surgical masks are rectangular, waterfall-pleated or soft-bill devices manufactured from selected non-woven materials (polypropylene or wet-laid cellulose) designed to provide optimal breathability, particulate filtration and a fluid-penetration barrier relative to the degree of protection required during intended use.

Intended Use of the Device: PRIMAGARD™ Surgical Masks are surgical apparel as identified in 21 CFR 878.4040 and are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The PRIMAGARD™ Surgical Masks may also be worn outside of the operating room for non-surgical procedure use.

Technological Characteristics: PRIMAGARD™ Surgical Masks are technologically similar to the predicate device (K001951) in that both devices consist of non-woven barrier materials selected and arranged in such a manner as to provide, at the time of design, and under the conditions of use, optimal breathability and particulate filtration. The PRIMAGARD™ Surgical Masks are an improvement in that non-woven materials production technologies have advanced and there is a better understanding of the physical aspects of the filtration capability. Accordingly, the non-woven products utilized in the PRIMAGARD™ Surgical Masks, when used in specific weight (gsm, grams per square meter) combinations are able to provide defined fluid resistance (as measured by the ASTM F2100-07 Standard Synthetic Blood Fluid Resistance test).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Raymond G. Marusyk
Director, Design and Development
PriMED Medical Products, Incorporated
#900, 10707-100 Avenue
Edmonton, Alberta, Canada T5J-3M1

AUG 11 2008

Re: K081633
Trade/Device Name: PrimaGARD™ 80, 120, 160 Surgical Face Masks
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: July 31, 2008
Received: August 1, 2008

Dear Mr. Marusyk:

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.

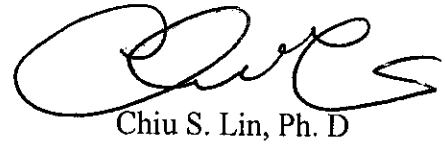
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

K081633

510(k) Number (if known)

K001951 (original for which modification is requested)

Device Name

PRIMAGARD™ Surgical Masks

Indications For Use

PRIMAGARD™ Surgical Masks (***see complete list of specific model names and numbers on following page***) are surgical apparel as identified in 21 CFR 878.4040 and are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801. 109)

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

510(k) Number: K081633

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List of PRIMAGARD™ Surgical Masks Included as Subjects of this Submission

Mask Name	Model Number
primaGARD 80	PG4-1201
primaGARD 80	PG4-2121
primaGARD 80	PG4-2421
primaGARD 80	PG4-4021
primaGARD 80	PG4-4241
primaGARD 120	PG4-1092
primaGARD 120	PG4-1592
primaGARD 120	PG4-2092
primaGARD 120	PG4-2592
primaGARD 160	PG4-1073
primaGARD 160	PG4-1573
primaGARD 160	PG4-2073
primaGARD 160	PG4-2473
primaGARD 160	PG4-3073
primaGARD 160	PG4-3473
primaGARD 160	PG4-3573
primaGARD 160	PG4-4073
primaGARD 160	PG4-5073