K051291

SEP 2 0 2005

510 (K) Summary

5.1 Device Trade Name: Non-Sterile Surgical Mask

5.2 Named and Address of Manufacturer:
A.R. Medicom Inc.
1200 55th Avenue,
Lachine, Quebec
H8T 3J8 Canada

Establishment Registration Number: 9680179

Contact Person:
Luc Trepanier
Corporate Director, Regulatory Affairs and Quality
Quality Assurance
Tel: (514) 636-6262
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E-mail: ltrepani@medicom.ca

5.3 Device Classification Name: Mask, Surgical

Classification/Panel: Class II, §878.4040

Classification Advisory Committee: General and Plastic Surgery

Product Code: FXX

Recognized Performance Standard
ASTM 2100-04
Refer to Appendix B for a list of applicable standards

5.4 Predicate Devices, 510(k) Number

1. Surgical Mask (non-sterile), K955513
2. Valumax Surgical Masks (Blue, Pink, Green, Yellow) K040333

5.5 Intended Use: The medical/surgical masks listed below are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of

	microorganism, body fluid, and particulate aerosol transfer. A list of mask models may be found in Appendix A. Further details regarding indications for use may be found in the Substantial Equivalence Summary in Section 8.
5.6 510(k) Statement	A 510(k) statement for the new device, as required by 21 CFR 93, is replaced with this 510(k) summary.
5.6 Truthful and Accurate Statement	A truthful and accurate statement as required by 21 CFR 807.87(j) may be found in Appendix D
5.7 Proposed Labeling	A draft copy of the proposed labeling may be found in Appendix E. Samples of the predicate device labeling may be found in Appendix F.
5.8 Device Description	The new surgical masks are pleated 3-ply masks. The outer layers are made with 100% spun-bound polypropylene (SBPP). The filter media is composed of 100% melt-blown polypropylene (MBPP). The inner layer is made of either 100% medical grade tissue paper or 100% SBPP. The ear loops are made of flat latex and fiberglass free elastic. The nosepieces are made of malleable aluminum wire. All of the materials used in the construction of the new masks are being used in currently marketed devices. Please refer to Section 6 for the complete device description summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

Mr. Luc Trepanier
Corporate Director, RA/QA
A.R. Medicom, Incorporated
1200 55th Avenue
Lachine, Quebec
H8T 3J8 CANADA

Re: K051291
Trade/Device Name: Non-Sterile Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Dated: August 25, 2005
Received: August 29, 2005

Dear Mr. Trepanier:

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.

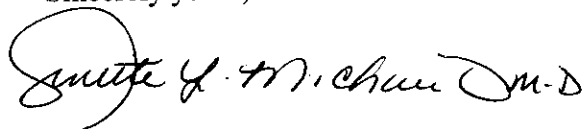
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Attachment SII.1

Indications for Use

510(k) Number: K051291

Device Name: Refer to Attachment SII-1

Indications For Use:

The medical/surgical masks listed below are indicated as a protective nose and mouth covering for health care workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid, and particulate aerosol transfer.

Prescription Use _____ **AND/OR** **Over-The Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephen H. Murphy 4D 9/20/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051291

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