MÖLNLYCKE HEALTH CARE

K102923

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 1 9 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: November 1, 2010

Applicant:
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Registration number: 3004763499
Owner/Operator Number: 8030877

Official Correspondent:
Caitlin Senter, MS, RAC
Regulatory Affairs Specialist
Tel: 678-250-7928
Fax: 678-245-7746
e-mail: caitlin.senter@molnlycke.com

Trade/Proprietary Name: Barrier® N95 Particulate Respirators, Models #4272 and #4273

Common Name: Particulate Respirator

Device Class: Class II

Regulation Number: 21 CFR 878.4040

Product Code: MSH

Predicate Device Name(s): Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 (K960778)

Description of Device:

Barrier® N95 Particulate Respirators, Models #4272 and #4273 are NIOSH certified (TC-84A-4350), trapezoid shaped respirators. Barrier® N95 Particulate Respirators, Models #4272 and #4273 consists of a flat folded disposable face mask that is a piece of three layered non-woven fabric folded in two. An aluminum filament is enclosed in a binding tape welding the top edge, which forms a conformable nose clamp for the purpose of shaping the mask to the contours of the face. It features elastic head bands, ultrasonically welded, to secure the masks in place for the wearer.

Intended Use/Indication for Use:

The devices 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.

Technological Characteristics:

The Barrier® N95 Particulate Respirators, Models #4272 and #4273 are substantially equivalent to the ISOLAIR APR Type N95 (K960778). Both devices have similar indications for use, materials, product design, and method of operation.

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In the manufacture of these devices, multiple standards were utilized. The Barrier® N95 Particulate Respirators, Models #4272 and #4273 characteristics are summarized below as compared to the requirements.

Characteristic	Standard
Fluid Resistance	The Barrier® N95 Particulate Respirators, Models #4272 and #4273 meet the requirements of ASTM F1862.
Particulate Filtration Efficiency	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)
Bacterial Filtration Efficiency	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)
Differential Pressure	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)
Flammability	The Barrier® N95 Particulate Respirators, Models #4272 and #4273 meet the requirements of 16 CFR 1610 Standard for Flammability of Clothing Textiles.
Cytotoxicity	The Barrier® N95 Particulate Respirators, Models #4272 and #4273 are not cytotoxic.
Irritation	The Barrier® N95 Particulate Respirators, Models #4272 and #4273 are not irritating.
Delayed-Type Hypersensitivity	The Barrier® N95 Particulate Respirators, Models #4272 and #4273 do not display any potential for sensitization.

Mölnlycke Health Care
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092 USA

Tel 678 250 7900
Fax 678 250 7984
www.molnlycke.com

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The table below presents the similarities and differences of the technological characteristics between the Barrier® N95 Particulate Respirators, Models #4272 and #4273 and the predicate device, Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 (K960778).

Feature	Barrier® N95 Particulate Respirators, Models #4272 and #4273 (Proposed Device)		Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 (Predicate Device)
510(k) Clearance	TBD		K960778
Manufacturer	Mölnlycke Health Care		LOUIS M. GERSON CO., INC
Common Name	Particulate Respirator		Particulate Respirator
Classification #	Class II		Class II
Classification Name	21 CFR 878.4040		21 CFR 878.4040
Product Code	MSH		MSH
Materials			
Outer Material	Polypropylene		Polyester
Inner Material	Polyethylene/Polypropylene		Polyester
Filter Media	Polypropylene		Polypropylene
Nose Clamp	Aluminum		Aluminum/ PVC foam
Binding/cover Tapes	Polyester		
Head Bands	Polyurethane (blue), ultrasonically welded		Rubber (green), stapled
Specifications and Dimensions	Small Mask Length 205 mm ± 5 mm Width 85 ± 5 mm Band Length 190 ± 5mm	Medium Mask Length 240 mm ± 5 mm Width 85 ± 5 mm Band Length 225 ± 5mm	Length 140 mm ± 6 mm Width 95 mm ± 6 mm Height 64 mm ± 3 mm Band Length (top) 318 mm ± 6 mm Band Length (bottom) 260 mm ± 6 mm
Mask Style	Trapezoid mask when folded, Duckbill when open		Cup shaped
Design Features	Single use, flat folded, single use, disposable respirator Longer vertical bottom length for more conformability to wearer, aluminum nose clamp to contour to the wearer		Single use, cup shaped respirator Contoured nosepiece Double stapled headstraps
NIOSH certification	TC 84A-4350 (Models #4272 and #4273)		TC 84A-160
Sterililty	Non-sterile		Non-sterile
Fluid Resistance	Pass		Pass
Particulate Filtration Efficiency	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)		NIOSH Certification Number: TC 84A-160
Bacterial Filtration Efficiency	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)		NIOSH Certification Number: TC 84A-160
Differential Pressure	NIOSH Certification Number: TC 84A-4350 (Models #4272 and #4273)		NIOSH Certification Number: TC 84A-160
Flammability	Pass		Not Known

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Performance Data:

The performance data are summarized above.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the performance testing, it can be concluded that the Barrier® N95 Particulate Respirators, Models #4272 and #4273 are equivalent to the Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 (K960778) predicate with respect to intended use, materials, design, technological characteristics and performance.

Mölnlycke Health Care
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092 USA

Tel 678 250 7900
Fax 678 250 7984
www.molnlycke.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Caitlin Senter
Regulatory Affairs Specialist
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

NOV 19 2010

Re: K102923
Trade/Device Name: Barrier® N95 Particulate Respirators, Models #4272 and #4273, NIOSH Certification TC-84A-4350
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: November 1, 2010
Received: November 2, 2010

Dear Ms. Senter:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

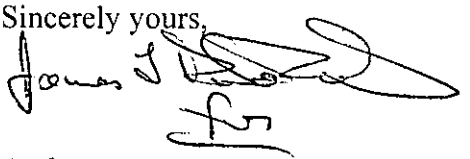
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MÖLNLYCKE HEALTH CARE

K102923

INDICATION FOR USE

NOV 19 2010

510(k) Number (if known): K102923

Device Name: Barrier® N95 Particulate Respirators, Models #4272 and #4273, NIOSH certification TC-84A-4350

Indication for Use:

The device is 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.

Prescription Use _____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _____ of _____

Elaine S. Maykall

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

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Mölnlycke Health Care
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092 USA

Tel 678 250 7900
Fax 678 250 7984
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