K102173

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June 16, 2010

Section 5. 510(k) Summary

Submitter:

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SEP 13 2010

Contact:

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Trade Name:

Model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask

Common Name:

Health Care N95 Particulate Respirator and Surgical Mask.

Classification:

Name – Surgical Apparel, as described in 21 CFR 878.4040.
Device Class – Class II
Product Code – MSH
CFR Section – 21 CFR 878.4040

Substantial Equivalency:

The model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask is found to be substantially equivalent to Moldex-Metric Health Care N95 Particulate Respirators models 1511, 1512, 1513, 1517 [(510(k) K061859] and models 3001N95-S, 3002N95-M, 3003N95-L, & 3004N95-LP [(510(k) K051182)] . These products have also been tested and approved by NIOSH as N95 Respirators.

Guidance Documents

Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA.

Device Description, Intended Use, Limitations, Comparisons of Predicate Devices, Risks to Health, Exclusions from Standards, & Performance Tests have all been included in this Summary Report as per the Guidance Document.

510(k) Summary (Continued)

Description:

The Moldex-Metric type N95 Healthcare Particulate Respirators and Surgical Masks are constructed from an extruded plastic mesh used in the outer cover and a nonwoven spunbond used in the inner and outer cover. The polypropylene melt blown filter media is layered between the inner and outer cover. The head strap is made of a non-latex rubber stapled to the mask. The inside nosepiece is a closed cell foam.

The model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask is approved by NIOSH in accordance with 42 CFR Part 84. The certification numbers is TC-84A-5227.

The type N95 must meet the prescribed test criteria which specifies the use of 0.055 to 0.095 micron diameter challenge and requiring a 95% efficiency or better and was tested by NIOSH in accordance with 42 CFR Part 84. The masks are resistant to synthetic blood as per ASTM F 1862 Standard Test method for Resistance of Medical Face Mask to Penetration by Synthetic Blood. Breathing resistance was tested by NIOSH in accordance to 42 CFR Part 84. The device has a Bacterial Filtration Efficiency greater than 99.9%. Testing was conducted using the Modified Green and Vesley Method for evaluation of bacterial filtration efficiency of surgical masks for the predicate devices.

Intended Use:

The model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask meets CDC Guidelines for TB Exposure Control within healthcare facilities. This device is also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.

Limitations:

This product does not eliminate the wearer from any risk of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

Comparison of Predicate Devices:

The outside cover of the previously cleared devices models 3001N95-S, 3002N95-M, 3003N95-L & 3004N95-LP incorporate a non-woven polypropylene material with a layer of an extruded plastic mesh and the Moldex-Metric models 1511, 1512, 1513, 1517 and new submitted model 1712 incorporate an extruded plastic mesh without the nonwoven material on the outer cover. The head strap color of the cleared device is the same as the Moldex-Metric device models for which clearance is being requested.

Moldex-Metrix model 1712 is only differs from the previously submitted models in that it has been designed as a flat fold type.

The Moldex-Metric type N95 Healthcare Particulate Respirators and Surgical Masks incorporate a highly efficient filter media and is 95% efficiency or better against aerosols that have a count median diameter of 0.055 – 0.095 microns which was scientifically established as the most penetrating particle size. The legally marketed devices previously cleared 510(k) are manufactured from similar materials.

Device and Predicate Devices Descriptions/ Comparisons

Description	Moldex-Metric Health Care N95 Particulate Respirator and Surgical Mask, model 1712	Moldex-Metric Health Care N95 Particulate Respirators and Surgical Masks, models 1511, 1512, 1513, 1517 (510k #K061859)	Moldex-Metrix Health Care N95 Particulate Respirators and Surgical Masks, models 3001N95-S, 3002N95-M, 3003N95-L, 3004N95-LP (510k #K051182)
Materials			
Outer Cover Fabrics	Spunbond polypropylene, Meltblown polypropylene	Spunbond polypropylene, Meltblown polypropylene	Spunbond polypropylene, Meltblown polypropylene
Nosepiece	Polyethylene foam	Polyethylene foam	Polyethylene foam
Headband	Various colors elastic, latex free	Various colors elastic, latex free	Various colors elastic, latex free
Specification & Dimensions	Medium/Large size (5 1/2" x 5 1/16")	Various sizes (4.75" - 5.625" circumference)	Various sizes (4.75" - 5.625" circumference)
Mask Style	Molded Cup/Flat Fold	Molded Cup	Molded Cup
Design Features	Dual synthetic rubber	Dual synthetic rubber	Dual synthetic rubber
NIOSH Certification#	TC-84A-5227	TC-84A-0013	TC-84A-4102
Intended Use	The model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask meets CDC Guidelines for TB Exposure Control within healthcare facilities. This device is also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.	The various models of Moldex-Metric Type N95 Healthcare Particulate Respirators and Surgical Masks meet CDC Guidelines for TB Exposure Control within healthcare facilities. These devices are also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.	The various models of Moldex-Metric Type N95 Healthcare Particulate Respirators and Surgical Masks meet CDC Guidelines for TB Exposure Control within healthcare facilities. These devices are also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.

Risks to Health

Performance Characteristics	Test Method	Acceptance criteria/ Results	Predicate Device Results	Predicate Device Results
		Moldex-Metric Health Care N95 Particulate Respirator and Surgical Mask	Moldex-Metric Health Care N95 Particulate Respirators and Surgical Masks various models (4)	Moldex-Metrix Health Care N95 Particulate Respirators and Surgical Masks various models (4)
Fluid Resistance Performance	ASTM 1862 – 00a	Model 1712 32 of 32 pass	Models 1511, 1512, 1513 and 1517 32 of 32 pass	Models 3001N95-S, 3002N95-M, 3003N95-L, 3004N95-LP 32 of 32 pass
Flammability Class *	16 CFR 1610	*Flame spread must be within upper and lower limits/ No flame spread on 10 of 10 samples, meets Class I	Flame spread must be within upper and lower limits/ No flame spread on 10 of 10 samples, meets Class I	Flame spread must be within upper and lower limits/ No flame spread on 10 of 10 samples, meets Class I
Filter Efficiency (%)	NIOSH, 42 CFR Part 84	≥ 95% Efficient/ average 98.95% efficient of 20 samples	≥ 95% Efficient/ average 98.58% efficient of 17 samples	≥ 95% Efficient/ average 99.11% efficient of 20 samples
Inhalation Breathing Resistance (mm H_2O)	NIOSH, 42 CFR Part 84	≤ 35.0 mm H_2O @ 85 lpm/ average 8.9 mm H_2O @ 85 lpm of 3 samples	≤ 35.0 mm H_2O @ 85 lpm/ average 10.3 mm H_2O @ 85 lpm of 3 samples	≤ 35.0 mm H_2O @ 85 lpm/ average 11.3 mm H_2O @ 85 lpm of 3 samples
Exhalation Breathing Resistance (mm H2O)	NIOSH, 42 CFR Part 84	≤ 25.0 mm H_2O @ 85 lpm/ average 8.9 mm H_2O @ 85 lpm of 3 samples	≤ 25.0 mm H_2O @ 85 lpm/ average 9.9 mm H_2O @ 85 lpm of 3 samples	≤ 25.0 mm H_2O @ 85 lpm/ average 16.9 mm H_2O @ 85 lpm of 5 samples
Biocompatibility *	ISO 10993 – 1	Cytotoxicity Score of 2 or less/score of 0	Cytotoxicity Score of 2 or less/score of 0	Cytotoxicity, score of 2 or less/ Score of 0
		Sensitization, Grade 1 (no different than control)/Grade 1	Sensitization, Grade 1 (no different than control)/Grade 1	Sensitization, Grade 1 (no different than control)/ Grade 1
		Primary Skin Irritation Negligible/Negligible	Primary Skin Irritation Negligible/Negligible	Primary Skin Irritation, Negligible/Negligible
Bacterial Filtration Efficiency *	Modified Greene and Vesley Method. J Bacteriol 83:663-667.	Test results show a bacterial filtration efficiency greater than 99.9%	Test results show a bacterial filtration efficiency greater than 99.9%	Greater than 99.9%

510(k) Summary (Continued)

Risks

Risk analysis is the same as the predicate devices. Approved under K061859 and K051182 the surgical mask device and the predicate device are made from the same material. The design of the mask with fold features was tested for Fluid Resistant in accordance with ASTM F 1862@ 160mmHg. All 32 of 32 pass and any risks would have been exposed at Fluid Resistant Testing.

Exclusions from Standards*

In accordance with ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and Testing (Third Edition, 2003-08-01), Table 1 – Initial evaluation of tests for consideration, since contact duration is A-Limited (<24 h), only the Cytotoxicity, Sensitization, and Irritation or Intracutaneous Reactivity tests were performed.

Performance Tests:

This product was tested and certified by NIOSH as an approved N95 Respirator. It meets all the requirements prescribed in 42 CFR Part 84 and is assigned TC-84A-5227

Tests Performed

1. Fluid Resistance - Resistance of Liquid (Synthetic Blood Penetration Resistance) ASTM F 1862.

2. Filtration Efficiency (Particulate and Bacterial) 42 CFR Part 84

3. Differential Pressure (Delta P) - Breathing Resistance 42 CFR Part 84

4. Flammability* 16 CFR 1610 (Class 1)

5. Biocompatibility* (tested on predicate devices)
   - Cytotoxicity
   - Sensitization
   - Irritation

6. Bacterial Filtration Efficiency* Modified Greene and Vesley Method. J Bacteriol 83:663-667.

* Tests were conducted on Predicate Devices which are made from the same material as models identified in this 510(k) submission.

Safety/ Effectiveness:

The device has a filtration equivalent to the previously cleared Moldex-Metric N95 Particulate Respirator and Surgical mask model 1511, 1512, 1513, 1517 [(510(k) K061859]. They are NIOSH approved and meet the CDC guidelines for TB exposure control.

Conclusion:

The basic construction and material used in the cleared devices are the same as in the new device. The cleared devices and the new device are also approved by NIOSH, and meets all other required tests. The Moldex-Metric type N95 Healthcare Particulate Respirator and Surgical Mask is substantially equivalent to those listed on page 11 – 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Moldex/Metric, Incorporated
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

SEP 13 2010

Re: K102173
Trade/Device Name: Model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: August 26, 2010
Received: August 31, 2010

Dear Mr. Lehtonen:

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,

for

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

K102173

Section 4. Indications for Use

SEP 13 2010

510(k) Number (if known):

Device Name: Model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask

Indications for Use: The model 1712 Moldex-Metric Type N95 Healthcare Particulate Respirator and Surgical Mask meets CDC Guidelines for TB Exposure Control within healthcare facilities. This device is also intended to be worn by healthcare personnel during surgical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Wilkes

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

510(k) Number: K102173