K061859

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June 27, 2006

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510(k) Summary

Submitter:

Inovel LLC
10111 W. Jefferson Blvd.
Culver City, CA 90232-3509

Contact:

William Wawrzyniak
Director Quality Assurance
Telephone: 866-546-6835 Ext. 705
Fax: 310-837-0468
E-mail: billw@inovelmedical.com

Trade Name:

Inovel Health Care N95 Particulate Respirators and Surgical Masks, various models.

Common Name:

Health Care N95 Particulate Respirators and Surgical Masks.

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:

Inovel Health Care N95 Particulate Respirators and Surgical Masks are found to be substantially equivalent to Inovel Health Care N95 Particulate Respirators model 3001N95-S, 3002N95-M, 3003N95-L and 3004N95-LP [(510(k) K051182]. These products have also been tested and approved by NIOSH as N95 Respirators.

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510(k) Summary (Continued)

Description:

The Inovel 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 Inovel type N95 Healthcare Particulate Respirators and Surgical Masks are approved by NIOSH in accordance with 42 CFR Part 84. The certification numbers is TC-84A-0013.

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. 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 devices have a Bacterial Filtration Efficiency greater than 99.9%. Testing was conducted by Nelson Laboratories using the Modified Green and Vesley Method for evaluation of bacterial filtration efficiency of surgical masks.

Intended Use:

The various models of Inovel 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.

Limitations:

These products do 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 incorporate a nonwoven polypropylene material with a layer of an extruded plastic mesh and the Inovel models 1511, 1512, 1513 and 1517 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 Inovel device models for which clearance is being requested.

The Inovel 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.

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510(k) Summary (continued)

Device and Predicate Devices Descriptions/ Comparisons

Description	Inovel Health Care N95 Particulate Respirators and Surgical Masks, models 1511, 1512, 1513, 1517	Inovel Health Care N95 Particulate Respirators and Surgical Masks, models 3001N95-S, 3002N95-M, 3003N95-L, 3004N95-LP
Materials		
Outer Cover Fabrics	Spunbond polypropylene, Meltblown polypropylene	Spunbond polypropylene, Meltblown polypropylene
Nosepiece	Polyethylene foam	Polyethylene foam
Headband	Various colors elastic, latex free	Various colors elastic, latex free
Specification & Dimensions	Overall width: 5 – 5 5/8 inches Overall height: 4 ¾ - 5 ½ inches	Overall width: 5 – 5 5/8 inches Overall height: 4 ¾ - 5 ½ inches
Mask Style	Molded Cup	Molded Cup
Design Features	Dual synthetic rubber	Dual synthetic rubber
NIOSH Certification#	TC-84A-0013	TC-84A-4102

Risks to Health

Performance Characteristics	Test Method	Acceptance criteria/ Results	Predicate Device Results
		Inovel Health Care N95 Particulate Respirators and Surgical Masks various models (4)	Inovel Health Care N95 Particulate Respirators and Surgical Masks various models (4)
Fluid Resistance Performance	ASTM 1862 – 00a	Models 1511, 1513 and 1517 32 of 32 pass Model 1512 31 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
Filter Efficiency (%)	NIOSH, 42 CFR Part 84	≥ 95% Efficient/ average 98.58% efficient of 17 samples	≥ 95% Efficient/ average 99.11% efficient of 20 samples
Breathing Resistance (mm H_2O)	NIOSH, 42 CFR Part 84	≤ 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
Biocompatibility *	ISO 10993 – 1	Cytotoxicity Same as predicate device	Cytotoxicity, score of 2 or less/ Score of 0
		Sensitization Same as predicate device	Sensitization, Grade 1 (no different than control)/ Grade 1
		Primary Skin Irritation Same as predicate device	Primary Skin Irritation, Negligible/Negligible
Bacterial Filtration Efficeincy	Modified Greene and Vesley Method. J Bacteriol 83:663-667.	Test results show a bacterial filtration efficiency greater than 99.9%	Greater than 99.9%

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

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510(k) Summary (Continued)

Performance Tests:

These products were 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-0013

Tests Performed	Laboratory
1. Fluid Resistance - Resistance of Liquid (Synthetic Blood Penetration Resistance) ASTM F 1862.	Inovel LLC
2. Filtration Efficiency (Particulate and Bacterial) 42 CFR Part 84	NIOSH
3. Differential Pressure (Delta P) - Breathing Resistance 42 CFR Part 84	NIOSH
4. Flammability 16 CFR 1610 (Class 1)	Nelson Laboratories
5. Biocompatibility* (tested on predicate devices)	Nelson Laboratories
• Cytotoxicity (ISO 10993-5)	Northview Pacific Laboratories, Inc. (Coordinated by Nelson Laboratories)
• Sensitization (ISO 10993-10)	Northview Pacific Laboratories, Inc. (Coordinated by Nelson Laboratories)
• Irritation (ISO 10993-10)	
6. Bacterial Filtration Efficiency Modified Greene and Vesley Method. J Bacteriol 83:663-667.	Nelson Laboratories

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

Safety/ Effectiveness:

The devices have a filtration equivalent to the previously cleared Inovel LLC N95 Particulate Respirator and Surgical mask models 3001N95-S, 3002N95-M, 3003N95-L and 3004N95-LP 510(k) number K051182. They are NIOSH approved and meet the CDC guidelines for TB and Avian Flu exposure control.

Conclusion:

The basic construction and material used in the cleared devices are the same as in the new devices. The cleared devices and the new devices are also approved by NIOSH, and meets all other required tests. The Inovel type N95 Healthcare Particulate Respirators and Surgical Masks are substantially equivalent to those listed on page 2 – 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

Inovel LLC
C/O Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road
Twinsburg, Ohio 44087

Re: K061859
Trade/Device Name: Health Care N95 Respirators and Surgical Masks Inovel Models 1511,1512,1513, & 1517
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: June 29, 2006
Received: June 30, 2006

Dear Mr. Devine:

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.

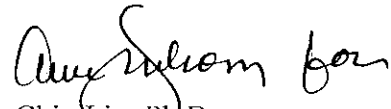
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K061859

Device Name: Health Care N95 Particulate Respirators and Surgical Masks
Inovel Models 1511,1512,1513 & 1517

Indications for Use:

The various models of Inovel 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.

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)

7/12/06

n Sign-Off)
n of Anesthesiology, General Hospital,
ion Control, Dental Devices
) Number: K061859