

K070168

II 510(k) Summary

APR 13 2007

Company Name and Address

Aearo Company
90 Mechanic Street
Southbridge, MA 01550

Contact Person

Ann Phillips
Quality Assurance Manager
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Manufacturing Facility

Available from Company

Date Prepared

January 12, 2007

Device Name

Trade Name – N9504C, N9504CS and N9514C N95 Respirators
Common Name – Surgical Mask or Surgical N95 Respirator

Classification

CFR Section – 21 CFR 878.4040
Device Class – Class II
Product Code – MSH – Surgical N95 Respirator

Device Description

These masks are molded cup masks, with a center layer of polypropylene meltblown material sandwiched by inner and outer layers of nonwoven material. The mask has 2 elastic headbands. No fiberglass media is used in this product.

Intended Use

These masks are intended for single use by operating room personnel or general health care workers for protection against microscopic organisms, body fluids and particulates. This would include use as a procedure mask, isolation mask or dental face mask.

Abbreviated 510(K)
For Aearo Company
N9504C, N9504CS and N9514C Surgical N95 Respirators

II 510(k)Summary (cont.)

N95 Respirators, N9504C, N9504CS and N9514C have been used in the industrial setting for over a year. They are NIOSH approved N95 respirators, approval numbers TC-84A-3715 and TC-84A-4272. OSHA regulations and the concerns relating to exposure of health care personnel to bloodborne pathogens have brought these types of products into the medical and dental care arenas.

Risk analysis was conducted as recommended in the Guidance Document for Surgical Masks. Adequacy of the fluid resistance was evaluated using ASTM 1862-00a. Testing was conducted at 80 mmHg. Acceptance criteria for this test is that 29 of 32 show no fluid penetration. Test results for these masks showed 32 of the 32 masks tested had no fluid penetration. Adequacy of the Mask for air exchange and as a respiratory barrier for bacteria were evaluated at the time of NIOSH certification. In addition, we conducted tests according to ASTM F2101-01, Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureas at Nelson Laboratories which showed a percent BFE of greater than 99.9% on all samples tested. Assessment of flammability of the mask was conducted according to 21 CFR Part 58 and it met Class I requirements showing no flame spread in the tests conducted by Nelson Laboratories. This conforms to the recommendation in the Guidance Document that only class I and class II flammability materials be used in surgical masks intended for use in the operating room. Finally, since surgical masks have parts that come into contact with the skin, biocompatibility was evaluated as described in ISO-10993. Three tests were conducted. Cytotoxicity was evaluated by Nelson Laboratories using the agar overlay method. None of the mask samples tested showed any detectable reactivity. Primary skin irritation was evaluated by AppTec Laboratory Services using rabbits, according to 16 CFR 1500 modified to use 3 animals instead of 6. No irritation was evident on intact or abraded skin after 24 or 72 hours. Delayed Hypersensitivity was evaluated by Northview Pacific Laboratories using the closed patch test NV SOP 16G-60. Albino guinea pigs were used for the test as required by ISO 10993-10, 2002. None of the Pleats Plus patched animals had any visible change at the test site 48 hours after the challenge dose.

This product meets the requirements of the tests recommended for evaluation and risk analysis outlined in the Guidance Document for Surgical Masks. Summary tables with test results for Pleats Plus and the predicate device (including acceptance criteria) and a comparison of the construction of Pleats Plus vs. the predicate device can be found on page 5. Copies of the test reports are in the appendix.

Pleats Plus N95 Respirators are substantially equivalent to the Gerson Isolair APR, type N95, Model 2735, 510(k) K960778, which is marketed for use as a Surgical Mask.

Abbreviated 510(K)
For Aearo Company
N9504C, N9504CS and N9514C Surgical N95 Respirators

510(k) Summary (cont.)

Device and Predicate Device Descriptions/Comparisons

Description	N9504C, N9504CS and N9514C Type N95 Masks	Gerson Isolair APR Type N95 Model 2735 , 510(K) K960778
Fabrics	White nonwoven polyester, meltblown polypropylene	White nonwoven polyester, meltblown polypropylene
Nosepiece	Aluminum	Aluminum
Headband	Yellow Elastic	Yellow Elastic
Specification and Dimensions	Small (13.5" circumference), Large (15.5" circumference)	Small (13.75" circumference)
Mask Style	Cup	Cup
Design Features	Dual elastic head strap	Dual elastic head strap
NIOSH Certification #	TC-84A-3715 (N9504C & N9504CS) TC-84A-4272 (N9514C)	TC-84A-160

Risks to Health

Performance Characteristics	Test Method	Acceptance Criteria/ Results	Predicate Device Results
		N9504C, N9504CS and N9514C Type N95 Masks	Gerson Isolair APR Type N95 Model 2735, 510(K) K960778
Fluid resistance Performance (mmHg)	ASTM F-1862 @ 80 mmHg	32 of 32 pass/ 32 of 32 pass	32/32 pass
Flammability class	21 CFR Part 58	Flame spread must be within upper and lower control limits/No flame spread on 10 of 10 samples, meets Class I	Meets Class I
Filter efficiency	NIOSH, 42CFR Part 84	≥95% Efficient / Average 97.36% (N9514C), 97.66%(N9504C), and 97.83%(N9504CS) efficient of 20 samples	Average 96.86% efficient of 20 samples
Breathing resistance:	NIOSH 42CFR Part 84	≤35.0 mm H ₂ O @ 85 lpm/ average 6.2 mm H ₂ O (N9514C), 7.6 mm H ₂ O (N9504C), and 8.0 mm H ₂ O (N9504CS) @85 lpm average of 3 samples each	Average 15.2 mm H ₂ O on 3 samples
Biocompatibility	ISO-10993-1	Cytotoxicity, score of 2 or less/ score of 0	N/A
		Sensitization, / No visible change, Score of 0	N/A
		Primary Skin Irritation/ Negligible, Score of 0	N/A



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ann L. Phillips
Quality Assurance Manager
Aearo Company
90 Mechanic Street
Southbridge, Massachusetts 01550

APR 16 2007

Re: K070168

Trade/Device Name: Surgical N95 Respirators N9504C, N9504CS and N9514C
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: March 22, 2007
Received: March 23, 2007

Dear Ms. Phillips:

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 (240) 276-3150 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): K070168

Device Name: Surgical N95 Respirators N9504C, N9504CS and N9514C

Indications For Use:

Aearo Surgical N95 Respirators, N9504C, N9504CS and N9514 are intended for single use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials. This includes use as a procedure mask, isolation mask or dental face mask. This device also meets CDC Guidelines for TB Exposure Control.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(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)

Shela P. Murphy MD

Director, Division of Respiratory and Critical Care Medicine, National Hospital of
Occupational Safety and Health

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