K041855

NOV 1 0 2004

Abbreviated 510(K)
For Aearo Company
Pleats Plus™ Surgical N95 Respirators

II 510(k) Summary

Company Name and Address

Aearo Company (submitter and manufacturing site)
90 Mechanic Street
Southbridge, MA 01550

Contact Person

Ann Phillips
Quality Assurance Manager
Telephone 508-764-5713
Fax 508-764-5242
E-Mail ann_phillips@aearo.com

Date Prepared

August 31, 2004
Modifications October 6,2004

Device Name

Trade Name – Pleats Plus N95 Respirator 1050 and 1050S
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 pleated, 3-ply masks, with a center layer of polypropylene meltblown material sandwiched by inner and outer layers of nonwoven material. The mask has 2 braided synthetic elastic headbands and a flexible wire tie nosepiece that allows the respirator to form to the bridge of the wearers nose. No fiberglass media is used in this product.

Intended Use

Pleats Plus is 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.

II 510(k)Summary (cont.)

Pleats Plus N95 Respirators have been used in the industrial setting for over 5 years. It is a NIOSH approved N95 respirator, approval number TC-84A-2630. 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 120 mmHg. Acceptance criteria for this test is that 29 of 32 show no fluid penetration. Test results for Pleats Plus showed 31 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 16 CFR 1610 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 Pleats Plus samples tested showed any detectable reactivity. Primary skin irritation was evaluated by NAMSA 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.

II 510(k) Summary (cont.)

Device and Predicate Device Descriptions/Comparisons

Description	Pleats Plus 1050 and 1050S	Gerson Isolair APR Type N95 Model 2735 , 510(K) K960778
Materials		
Fabrics	White spunbond polypropylene, meltblown polypropylene	White nonwoven polyester, meltblown polypropylene
Nosepiece	Tie wire	Aluminium
Headband	White Elastic	Yellow Elastic
Specification and Dimensions	Small (13.5" circumference), Large (15.5" circumference)	Small (13.75" circumference)
Mask Style	Flat pleated	Cup
Design Features	Dual elastic head strap	Dual elastic head strap
NIOSH Certification #	TC-84A-2630	TC-84A-160

Risks to Health

Performance Characteristics	Test Method	Acceptance Criteria/ Results	Predicate Device Results
		Pleats Plus 1050 and 1050S	Gerson Isolair APR Type N95 Model 2735, 510(K) K960778
Fluid resistance Performance (mmHg)	ASTM 1862-00a @ 120mmHg	29 of 32 pass/ 31 of 32 pass	32/32 pass
Flammability class	16 CFR 1610	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 99.11% efficient of 20 samples	Average 96.86% efficient of 20 samples
Breathing resistance:	NIOSH 42CFR Part 84	≤35.0 mm H_20 @ 85 lpm/ average 3.5 mm H_20 @85 lpm of 3 samples	Average 15.2 mm H_20 of 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2004

Aearo Company
C/O Mr. Bahram Barzideh
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747-3081

Re: K041855
Trade/Device Name: Pleats Plus™ N95 Respirator 1050 and 1050S
Surgical N95 Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: October 8, 2004
Received: October 26, 2004

Dear Mr. Barzideh:

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/dsma/dsmamain.html

Sincerely yours,

Michael M.D. FOR DR. CHIU LIN
ACTING CHIEF, INFECTION CONTROL BRA

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

Abbreviated 510(K)
For Aearo Company
Pleats Plus™ Surgical N95 Respirators

Intended Use:

510(k) Number: K041855

Device Name: Pleats Plus™ N95 Respirator 1050 and 1050S
Surgical N95 Respirator

Indications for Use:

The Pleats Plus™ 1050 and 1050S N95 Respirators and Surgical Masks 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 _____ 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)

Janette Y. Michaud M.D. FOR DR. CHIU LIN
ACTING CHIEF, INFECTION CONTROL BRANCH

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

510(k) Number K041855