3M Health Care Business

3M Center, Bldg. 0275-05-W-06
St. Paul, MN 55144-1000
651 733 1110

K121069

510(k) Summary

FEB 1 1 2013

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:	February 11, 2013
Applicant:	3M Health Care Building 275 – 5W – 06 3M Center St. Paul, MN 55144 Establishment registration number: 2110898
Official Correspondent:	Jizhong Jin, RAC Regulatory Affairs Specialist Tel: 651-733-6655 Fax: 651-737-5320 e-mail: jjin1@mmm.com
Trade/Proprietary Name:	3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Model 1805/1805S
Common Name:	Surgical Respirator
Classification Name:	Surgical Apparel
Device Class:	Class II
Regulation Number:	21 CFR 878.4040
Product Code:	MSH
Predicate Device Name:	3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870

Description of Device:

The 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1805/1805S is an N95 particulate respirator. Particulate respirators help reduce wearer exposure to certain airborne particles, including those generated by electrocautery, laser surgery and other powered medical instruments. This

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respirator has a filter efficiency level of at least 95% against particulate aerosols free of oil[†]. As a surgical mask, it is designed to be fluid resistant to splash and spatter of blood and other infectious materials[‡] and meets > 99% bacterial filtration efficiency (BFE) [±]. It is cleared to be worn in surgery. It can fit a wide range of face sizes.

This respirator contains no components made from natural rubber latex.

[†] Tested against 0.3 micron particles (mass median aerodynamic diameter) per U.S. 42 CFR 84.
[‡] Meets ASTM Fluid Resistant Challenge F1862.
[±] Meets ASTM Standard Test Method for Bacterial Filtration Efficiency F2101.

Intended use:

3M™ VFlex™Health Care Particulate Respirator and Surgical Mask 1805/1805S 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.

Technological Characteristics:

The 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Model 1805/1805S substantially equivalent to the 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870. The product proposed under this premarket notification submission is composed of the same or similar components, has same or similar performance features, same intended use and indications for use as the predicate device. There are no new questions of safety or effectiveness.

Table of Comparison of the 3M™ VFlex™Health Care Particulate Respirator and Surgical Mask, Model 1805/1805S and the 3M Health Care Particulate Respirator and Surgical Mask, Model 1870

Description	**Predicate Device** 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870 (K063023)	**Subject Device** 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Model 1805/1805S
Intended Use	Surgical Mask/Respirator	Surgical Mask/Respirator

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Materials		
Construction Technology	Multi-Layer	Multi-Layer
Outside cover web	Polypropylene spunbond	Polypropylene spunbond
Stiffener web	Polypropylene spunbond	NA
Filter web	Polypropylene	Polypropylene
Inner web	Polypropylene	Polypropylene
Nose-Clip	Aluminum	Aluminum
Staple	Steel	Steel
Headband	Polyisoprene	Polyisoprene
Nose foam	Polyurethane	NA
Specifications and Dimensions		
Audit of NaCl Load Test	≤5.0%	≤5.0%
Dimensions	See appendix 1	See appendix 2
Product style	Flat fold	Flat fold
Design Features		
Fluid Resistance (ASTM F1862)	Pass @ 160 mmHg	Pass @ 120 mmHg
Flammability class 16 CFR Part 1610	Class I	Class I
NIOSH Certificate	N95 classification 84A-3884	N95 classification 84A-5469 for model 1805 84A-5470 for model 1805S

The product proposed under this premarket notification submission is similar in design, is composed of the same or similar components and is manufactured under the same quality management system as the predicate device.

The product under this premarket notification submission has the same or similar performance characteristics. They are both fluid resistant with the flammability of class I. They are also NIOSH certified with the same filtration efficiency.

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Based on the product design, the components of the product, the performance characteristics of the product, 3M concluded that the product proposed under this premarket notification submission is substantially equivalent to the predicate product. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 11, 2013

Mr. Jizhong Jin, RAC
Regulatory Affairs Specialist
3M Health Care
3M Center, Building 275 – 5W – 06
ST. PAUL MN 55144

Re: K121069
Trade/Device Name: 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Model 1805 & 1805S
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: January 21, 2013
Received: January 28, 2013

Dear Mr. Jin:

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.

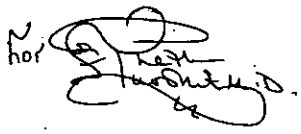
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121069

4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K121069

Device Name: 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Model 1805 & 1805S

Indications for Use:

3M™ VFlex™Health Care Particulate Respirator and Surgical Mask 1805/1805S 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 _____ (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)

Elizabeth F. Claverie
2013.02.07 15:07:14 -05'00'

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

510(k) Number: K121069