



Food and Drug Administration
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August 10, 2017

3M Health Care
Linda Johnsen
Regulatory Affairs Specialist
3M Center, 2510 Conway Ave., Building 275-5W-06
St. Paul, Minnesota 55144

Re: K171116
Trade/Device Name: 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask,
Models 1804/1804S
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: MSH
Dated: July 12, 2017
Received: July 13, 2017

Dear Linda Johnsen:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tara A. Ryan -S
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for
Lori Wiggins
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K171116

Device Name

3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask , Models 1804/1804S

Indications for Use (Describe)

3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804/1804S is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary - K171116

| | |
|------------------------------|--|
| Sponsor Information | 3M Health Care 2500 Conway Ave 3M Center, Building 275-5W-06 St. Paul, MN 55144 |
| Contact Person | Linda Johnsen Title: Regulatory Affairs Specialist Phone Number: (651) 737-4376 Fax Number: (651) 737-5320 |
| Date of Summary | August 9, 2017 |
| Common Name | Surgical N95 Respirator |
| Classification Name | Surgical Apparel |
| Proprietary Name | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Models 1804/1804S |
| Review Panel | General Hospital |
| Product Code | MSH |
| Device Classification | Class II per 21 CFR §878.4040 |
| Predicate Device | 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870 cleared under K063023. |
| Intended Use: | The 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804/1804S is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material. |

Device Description:

The 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Models 1804/1804S are provided as a flat-folded Surgical N95 Respirator composed of multi layers of materials consisting of polypropylene spunbond (inner web), polypropylene (filter web), polypropylene spunbond (outer web). The product contains an aluminum nose clip within the layers of the top edge of the product to conform to the contours of the face. In addition, the product contains two steel staples used to secure the two polyisoprene elastic headbands (not made with natural rubber latex) to the product and the headbands are to secure the product in place on the wearer. The products are provided only in white and provided in two sizes one being small.

The 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, 1804/1804S is an N95 particulate respirator. Particulate respirators help reduce the wearer exposure to certain airborne particles, including those generated by electrocautery, laser surgery and other powered medical instruments. This 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. CDC guidelines state N95 respirators may be used for *M. tuberculosis*.*

Not 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 80 mmHg.

± Meets ASTM Standard Test Method for Bacterial Filtration Efficiency F2101.

* Centers for Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask
Models 1804/1804S - Traditional 510(k) Submission

Comparison Table:

A comparison between the proposed submission devices and predicate device is shown in the table below for the purpose of demonstrating equivalence as to efficacy and safety.

Table 1 Comparison Table

| Feature | 510(K) Submission Device 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask Model 1804 | 510(K) Submission Device 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask- Small Model 1804S | Predicate Device (K063023) 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870 |
|--------------------------------------|--|--|--|
| Intended Use | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804 is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material. | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask- Small 1804S is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate material. | This product meets CDC guidelines for <i>M. tuberculosis</i> exposure control. As a respirator, it is intended to help reduce wearer exposure to certain airborne particles, including those generated by electrocautery, laser surgery, and other powered medical instruments. As a surgical mask, it is designed to be fluid resistant to splash and splatter of blood and other infectious materials. |
| Materials | | | |
| Outer Cover Web | Polypropylene Spunbond | Polypropylene Spunbond | Polypropylene Spunbond |
| Stiffener Web | N/A | N/A | Polypropylene Spunbond |
| Filter Web | Polypropylene | Polypropylene | Polypropylene |
| Inner Web | Polypropylene Spunbond | Polypropylene Spunbond | Polypropylene Spunbond |
| Nose-Clip | Aluminum | Aluminum | Aluminum |
| Staple | Steel | Steel | Steel |
| Headband | Polyisoprene | Polyisoprene | Polyisoprene |
| Nose Foam | N/A | N/A | Polyurethane |
| Surgical N95 Respirator Style | | | |
| Fold | Cone shape provided as flat fold | Cone shape provided as flat fold | Cone shaped provided as flat fold |
| Layers | Multi | Multi | Multi |

3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask
Models 1804/1804S - Traditional 510(k) Submission

| Design Feature | | | |
|--|--|--|---|
| Headband | Polyisoprene rubber elastic band | Polyisoprene rubber elastic band | Polyisoprene rubber elastic band |
| Sterility | | | |
| | Non Sterile Single Use | Non Sterile Single Use | Non Sterile Single Use |
| Specifications and Dimensions | | | |
| Audit of NaCl Load Test | ≤ 5.0% | ≤ 5.0% | ≤ 5.0% |
| Color | White | White | White |
| Length | 255mm | 235mm | 208mm |
| Headband Length | 240mm | 220mm | 193mm |
| Performance Specifications | | | |
| Particulate Filtration Efficiency (PFE) | NIOSH Certification N95 Classification 1804 TC-84A-7789 | NIOSH Certification N95 Classification 1804S TC-84A-7790 | NIOSH Certification N95 Classification 84A-3884 |
| Differential Pressure Delta P | NIOSH Certification N95 Classification 1804 TC-84A-7789 | NIOSH Certification N95 Classification 1804S TC-84A-7790 | NIOSH Certification N95 Classification 84A-3884 |
| Fluid Resistance (ASTM F1862) | Pass 80 mmHg | Pass 80 mmHg | Pass 160 mmHg |
| Bacterial Filtration Efficiency (BFE) (ASTM F2101) | ≥ 99 (%) | ≥ 99 (%) | ≥ 99 (%) |
| Flammability (CFR 16 1610) | Class I | Class I | Class I |
| NIOSH Certification | | | |
| N95 Respirator | N95 Classification 1804 TC-84A-7789 | N95 Classification 1804S TC-84A-7790 | N95 Classification 84A-3884 |
| Biocompatibility | | | |
| ISO109331-1 | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask (1804) has been evaluated according to guidelines established by ISO 10993-1:2009. 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask - Small (1804S) has been evaluated according to guidelines established by ISO 10993-1:2009. 3M™ VFlex™ Health Care Particulate | The material was determined to have acceptable biocompatibility for a surface contacting device with prolonged (< 30 days) contact. |

3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask
 Models 1804/1804S - Traditional 510(k) Submission

| | | | |
|--|--|---|--|
| | <p>(1804) is categorized as a surface device having prolonged (< 30 days) contact with intact skin. As such, the guidance suggests that cytotoxicity, irritation and sensitization testing be performed. 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask (1804) as to risk of adverse reactions is low for under the conditions of study the device is non-irritating and non-sensitizing. Results for cytotoxicity ranged from non-cytotoxic to moderately cytotoxic. Cytotoxicity is defined by ISO 10993-5 as a screening test, and on the basis of the totality of the data there is no increased health risk based on these results.</p> | <p>Respirator and Surgical Mask - Small (1804S) is categorized as a surface device having prolonged (< 30 days) contact with intact skin. As such, the guidance suggests that cytotoxicity, irritation and sensitization testing be performed. 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask - Small (1804S) as to risk of adverse reactions is low for under the conditions of study the device is non-irritating and non-sensitizing. Results for cytotoxicity ranged from non-cytotoxic to moderately cytotoxic. Cytotoxicity is defined by ISO 10993-5 as a screening test, and on the basis of the totality of the data there is no increased health risk based on these results.</p> | |
|--|--|---|--|

Technological Characteristics:

The technological characteristics of the submission device is substantially equivalent to the predicate device for they are N95 NIOSH-certified respirators and have undergone testing according to recognized standards ASTM F1862, ASTM F2101 and flammability testing in accordance with 16 CFR 1610. Their materials are determined to have acceptable biocompatibility for a surface contacting device with prolonged (< 30 days) contact in accordance with ISO10993-1.

Conclusion:

The proposed submission devices 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Models 1804/1804S are similar in design, intended use, technological characteristics and components as the predicate 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870. The submission and predicate devices are N95 NIOSH-certified respirators.

The biocompatibility testing and toxicology assessment supports the 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Models 1804/1804S being biocompatible as the predicate 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870.

Based on the above, the proposed submission devices 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask, Models 1804/1804S is substantially equivalent to the predicate 3M™ Health Care Particulate Respirator and Surgical Mask, Model 1870.