FDA exempted certain class II surgical masks from premarket notification requirements, subject to conditions and limitations (83 FR 22846). Specifically, single-use, disposable respiratory protective devices (i.e., N95s) used in a healthcare setting and worn by healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material that are regulated under procode MSH are exempt from premarket notification.

FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information, please contact elizabeth.claverie@fda.hhs.gov or the Infection Control Devices Branch at 301-796-5580.

Guidance for Industry and FDA Staff

Surgical Masks - Premarket Notification [510(k)] Submissions

Document issued on: March 5, 2004 and a correction posted on July 14, 2004.

The draft of this document was issued on May 15, 2003.

This guidance supersedes "Draft Guidance for Industry and FDA Reviewers on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Mask" issued January 16, 1998.

For questions regarding this document, please contact Chiu S. Lin, Ph.D. at 240-276-3700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Infection Control Devices Branch
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation

Contains Nonbinding Recommendations

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 03D-0137. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/094.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (**094**) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Contains Nonbinding Recommendations

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Guidance for Industry and FDA Staff

Surgical Masks - Premarket Notification [510(k)] Submissions

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

FDA has developed this guidance document to assist industry in preparing premarket notification submissions for surgical masks and other masks including isolation masks, procedure masks, and dental masks. These devices may be used by healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe should be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at http://www.fda.gov/cdrh/modact/leastburdensome.html.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Background

A manufacturer who intends to market a device of this generic type should conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, and obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.81 and 807.87).

This guidance document identifies the classification regulation and product codes for surgical masks (refer to **Section 4**). In addition, other sections of this guidance document provide additional information to manufacturers on addressing risks related to these devices in premarket notifications (510(k)s).

This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and "**How to Prepare a 510(k) Submission**" on FDA Device Advice at http://www.fda.gov/cdrh/devadvice/314.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**," http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once FDA has issued a guidance document addressing that device. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its

intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used. We recommend that you also include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 11** for specific information that we recommend you include in labeling.)

Summary report

We recommend that the summary report contain a:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to **Section 5** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[1]

- Description of device design requirements.

- Identification of the risk analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)

[1] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

- Discussion of the device characteristics that address the risks identified in this guidance document, as well as any additional risks identified in your risk analysis.

- Brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-10** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[2] (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

- If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:
    - statement that testing will be conducted and meet specified acceptance criteria before the product is marketed; or
    - declaration of conformity to the standard.[3]

  Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

We may request additional information about aspects of the device's performance characteristics or information to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we

[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[3] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you may submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

4. Scope

The scope of this document is limited to the following devices described in 21 CFR §878.4040(b) class II, product codes:

FXX Surgical Mask

MSH Surgical N95 NIOSH certified Respirator

Surgical Mask

A surgical mask covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The surgical masks referenced in this guidance document include masks that are labeled as a surgical, laser, isolation, dental or medical procedure masks with or without a face shield.

Surgical Respirator "N95 NIOSH Certified"

A surgical respirator is fitted to the user's face, forming a seal that provides a physical barrier to fluids, particulate materials, and aerosols. If you wish to label your device "N95 NIOSH Certified," please refer to the (NIOSH) website at http://www.cdc.gov/niosh/status.html for information about NIOSH's Certification Program Support for Respirator Manufacturers.

5. Device Description

We recommend that you identify your device by regulation and product code and compare your device with the predicate device using a tabular format as shown in the example below. We recommend that you provide information to show how the new device is both similar to and different from the legally marketed device. Side by side comparisons, whenever possible, are desirable. We also recommend that you describe how any differences may affect the comparative safety and performance of the new device.

Device and Predicate Device Descriptions

Description	**Your Device**	**Predicate** (with 510(k) number, if available)
Materials		
Specifications and dimensions		
Mask style		
Design features		
NIOSH certification number (when available)		

We recommend that you include the following descriptive information in the comparison table:

Material Composition

We recommend that you describe the material composition of the mask. A description of material composition may include the following:

Type of fabric:

- polypropylene
- spunbonded, meltblown, or wetlaid.

Other materials:

- metals, for example, used in nose features
- colorants
- elastic materials, e.g., used in ear loops
- foam and other anti-fog materials, if any
- face shield materials, if any.

Specifications and Dimensions

We recommend that you provide the following information about your device and any add-on features such as a face shield or wrap-around visor:

- size
- dimensions

- tensile strength
- other specifications relevant to user needs, e.g., impact resistance

Design features

We recommend that you describe the design features of your mask, such as:

- tie-on or ear loops
- elastic
- face shield attached

Mask Styles

We recommend that you identify the style of your mask, e.g., duck bill, flat pleated, cone shaped, pouch.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the surgical masks addressed in this document. The information we recommend you include in your 510(k) to address these identified risks are given in this guidance document, as shown in the table below. We recommend that you conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device. The 510(k) should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
Inadequate fluid resistance	Section 7
Inadequate barrier for bacteria	Section 8
Inadequate air exchange (differential pressure)	Section 9
Flammability	Section 10
Inadequate respiratory barrier for bacteria	NIOSH certification

Surgical masks include parts that have prolonged contact with intact skin. We recommend that

you evaluate the biocompatibility of the materials in these parts as described in the standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for limited contact devices, contacting intact skin. We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30). You should select tests appropriate for the duration and level of contact with your device. If identical materials are used in a predicate device with the same type and duration of skin contact, you may identify the predicate device in lieu of performing biocompatibility testing.

For a surgical mask that is also an N95 Respirator and certified by NIOSH as a respirator, you may submit the NIOSH certification number in lieu of filter efficiency performance (Section 8) and differential pressure (Section 9).

7. Fluid Resistance

Fluid resistance is the ability of the mask's material to resist the penetration of blood and body fluids. We recommend that you evaluate the fluid resistance of your device using the standard listed below.

- ASTM F 1862: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood

According to ASTM F 1862, surgical masks are tested on a pass/fail basis at three velocities corresponding to the range of human blood pressure (80, 120, 160 mm Hg). Fluid resistance may be claimed if the device passes ASTM F1862 at any levels. Surgical masks that show passing results at higher velocities are more fluid resistant.

8. Filtration Efficiency

For surgical masks that are not NIOSH certified N95 Respirators, we recommend that you evaluate filter efficiency performance and bacterial filtration efficiency. For surgical masks that are NIOSH certified N95 Respirators, you may submit your NIOSH certification number in lieu of this information.

Particulate Filtration Efficiency

We recommend that you conduct a particle challenge study using 0.1-Micron Polystyrene Latex Spheres. This in vitro test challenges the mask with unneutralized 0.1-micron polystyrene latex spheres and measures penetration. The use of latex spheres provides an appropriately rigorous test for evaluating a submicron efficiency performance (ASTM F 1215-89 Standard Test Method for Determining the Initial Efficiency of Flatsheet Filter

Medium in an Airflow Using Latex Spheres.).

Bacterial Filtration Efficiency

Bacterial Filtration Efficiency (BFE) is a measure of the ability of the mask's material to prevent the passage of aerosolized bacteria. BFE is expressed in the percentage of a known quantity that does not pass the mask material at a given aerosol flow rate. We recommend that you evaluate the BFE of your device using one of the test methods or standards listed below.

- Bacterial Penetration (aerosol filtration) - Mil- M369454C, Military Specifications: Surgical Mask, disposable (June 12, 1975).
- Modified Greene and Vesley Method: Method for evaluation of bacterial filtration efficiency of surgical masks. J Bacteriol 83:663-667. (1962).
- ASTM F2101-01 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of surgical masks using a Biological Aerosol of Staphylococcus aureus.

9. Differential Pressure (Delta-P) Test

For surgical masks that are not NIOSH certified N95 Respirators, we recommend that you evaluate differential pressure. For surgical masks that are NIOSH certified N95 Respirators, you may submit your NIOSH certification number in lieu of this information.

Differential Pressure (Delta-P) is the measured pressure drop across a surgical facemask material. Delta-P determines the resistance of the surgical facemask to air flowing through the mask. Pressure drop also relates to the breathability and comfort of the surgical mask. In general, a lower Delta-P translates to increased breathability.

- MIL-M-36945C 4.4.1.1.1 Method 1 Military Specifications: Surgical Mask, disposable (June 12, 1975)

When reporting Delta-P, report face velocity or sample size and flow rates referencing the test method used.

Comfort Scale used in Delta-P testing

Score	Perception
Above 5.0	hot
4.0 to 5.0	very warm
3.0 to 4.0	warm
2.0 to 3.0	cool
1.0 to 2.0	very cool

10. Flammability Testing

We recommend using one of the standards below to determine the flammability by class.

- CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles
- NFPA Standard 702-1980: Standard for Classification of Flammability of Wearing Apparel [4]
- UL 2154**:** Test that measures the level of atmospheric oxygen required to propagate flame when ignition is caused by an electrosurgery unit or laser. Higher levels of oxygen required for flame propagation indicate materials which are more flame resistant for electrosurgery or laser procedures.

We recommend that Class 1 and Class 2 flammability materials be used in surgical masks intended for use in the operating room.

FDA believes that devices with a NFPA Class 4 rating are not appropriate for use in the operating room. There are many potential ignition sources in the operating room, including surgical lasers, electrosurgical units, endoscopic fiberoptics, and high-energy electro-medical devices. All materials will burn if a high intensity heat source is applied to them, especially in the presence of elevated oxygen levels.

[4] In the past, an NFPA test method was used to assess flame-spread rate in textile. Although this document was removed from NFPA's list of "active" standards in 1987, the test is still referenced by many submitters.

11. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[5]

Intended Use

We recommend that you clearly state the intended use of your device, and identify whether it is a combination surgical mask /NIOSH certified N95 Respirator. We recommend that you also describe the indications for use, such as whether the mask is an isolation mask, procedure mask, or dental face mask.

We also recommend that you state whether your device is intended to be a reusable device or a single use disposable device.

Warning

For a Class 3 flammability surgical mask, we recommend that you include a flammability warning, such as one of the following examples:

This device does not meet 16 CFR 1610, NFPA, or CPSC flammability standards.

This device may burn when used in the presence of high intensity heat source or flammable gas.

[5] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a device is introduced into interstate commerce. In addition, final labeling for prescription devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Appendix I Abbreviations

ASTM	American Society for Testing and Materials
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CPSC	Consumer Products Safety Commission
DSMICA	Division of Small Manufacturers, International and Consumer Assistance
ISO	International Organization for Standardization
NFPA	National Fire Protection Association
NIOSH	National Institute of Occupational Safety and Health
ODE	Office of Device Evaluation
OSHA	Occupational Safety and Health Administration
SMDA	Safe Medical Devices Act of 1990
UL	Underwriters Laboratory, Inc.

Appendix II. Summary Report Sample Formats

You may use the following formats, as applicable to your device, for your summary report. Your acceptance criteria may be based on the performance characteristics of a legally marketed predicate. If possible, you should provide the 510(k) number for the predicate. We recommend that the predicate device(s) you choose be as close in intended use, design, and technology to the new surgical mask as possible.

For surgical masks that are not NIOSH certified N95 Respirators we recommend the format below.

Performance Characteristics	Test Method	Acceptance Criteria or Results
Fluid Resistance Performance (mmHg)		
Particulate Filtration Efficiency Performance (%)		
Bacterial Filtration Efficiency Performance (%)		
Differential Pressure (Delta-P) ($mm\ H_2O/cm^2$)		
Flammability class Class 1		

For surgical masks that are NIOSH certified N95 Respirators we recommend the format below.

Performance Characteristics	Test Method	Acceptance Criteria or Results
Fluid Resistance Performance (mmHg)		

Flammability class		