



# **FDA Regulatory Process for Premarket [510(k)] Submission: General and Antimicrobial containing Surgical N95 Respirators**



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Food and Drug Administration



FDA/CDRH is responsible for regulating medical devices to ensure that they provide a reasonable assurance of safety and effectiveness and to approve or clear these devices for interstate commerce.



## **FDA Definition of Medical Devices**

Medical devices are “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or animals”



## **FDA/CDRH Responsibilities for Medical Device Regulation**

- Evaluate and approve/clear medical devices for marketing to ensure that they are safe
- Inspect manufacturing facilities to ensure the quality of devices
- Take corrective actions to remove devices from commercial distribution when they are unsafe, misbranded or adulterated
- Educate consumers



# FDA Classification of Medical Devices

- Class I Low Risk
- Class II Intermediate Risk
- Class III High Risk



# **FDA Regulation of Medical Devices**

## **General Controls**

- Establishment Registration
- Medical Device Listing
- Quality System Regulation
- Labeling Requirements
- Medical Device Reporting of Adverse Events



# **FDA Regulation of Medical Devices Special Controls**

- Regulatory Performance Standards
- Special Labeling Requirements
- FDA Guidance Documents
- Special User Education and Training
- Patient Registries
- Postmarket Surveillance





## **Premarket Notification for FDA Regulated Devices**

A premarket notification [510(k)] is a marketing application submitted to FDA to demonstrate that the medical device described is substantially equivalent to a legally marketed device that was or is currently on the US market.



## **510(k) Premarket Notification Submission**

- Identification and Description of the Device
- Identification of and Comparison to a Legally Marketed Predicate Device
- Statement of Indications for Use
- Risk Analysis/Mitigation Demonstrated by Performance Testing
- Labeling Review



# Personal Protective Equipment Regulated by FDA

- Class II Devices
- Subject to Premarket Notification Submission [510(k)]
- Surgical Masks and N95 Surgical Respirators



# 510(k) Review Criteria for N95 Respirators

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June 18, 2013

Presented at the CDC meeting



## Overview

### **Types of N95 Respirators regulated by FDA:**

- Surgical N95 Respirators (Health Care Use)
- N95 Respirators used during Public Health Medical Emergencies (General Public Use)
- N95 Respirators with added Antimicrobial Agents



# **Surgical N95 Respirators**



## **Subject to Premarket Notification [510(k)]** (Class II devices under CFR 21 880.4040)

“Surgical apparel are devices that are 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.”



# N95 Respirators

## Parallel Authority

- N95 Respirators are Certified by NIOSH as Filtering Face Piece Respirators
- Cleared by the FDA as **“Surgical”** N95 Respirators





## 510(k) Review Process

### FDA's Guidance Document:

- Surgical N95 respirators to be cleared for marketing address the performance and safety issues described in the Guidance Document “Surgical Masks – Premarket Notification [510(k)] Submissions”
- This document may be found at:  
[www.fda.gov/cdrh/ode/guidance/094.pdf](http://www.fda.gov/cdrh/ode/guidance/094.pdf).



## 510(k) Review Process

- Material Composition
- Sizes, Models
- Dimensions
- Design Features



# 510(k) Review Process

Performance criteria

- Fluid Resistance
- Filtration Efficiency
  - Particle Filtration Efficiency (NIOSH Certification)
  - Bacterial Filtration Efficiency
  - Viral Filtration Efficiency (optional)
- Flammability
- Differential Pressure (NIOSH Certification)
- Biocompatibility
  - Irritation
  - Sensitization



# **N95 Respirators for General Public Use during Medical Health Emergencies**



# Considerations

- **Fit Assessment** - evaluation of the fit characteristics of the respirator
- FDA's Special Controls guidance document may be found at:  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071398.htm>



# **N95 Respirators with Added Antimicrobial Agents**

**Note: The following presentation should not be considered as  
Guidance from FDA**



## Considerations for 510(k) Review Process

- Mode of Action?
- Minimum Effective Concentration?
- Antimicrobial efficacy against the claimed microorganisms?
- Sustainability of the antimicrobial efficacy over repeated microbial exposures?



## Information on Antimicrobial Agent

- Whether the Antimicrobial agent been previously approved by FDA?
- What is the approved indication?
- What is the effective concentration?





## Antimicrobial Efficacy

- Performance measured by quantitative testing?
- Antimicrobial efficacy and the effect of storage period evaluated?



## Performance Testing considerations

- Support the indications for use?
- How could *in vitro* testing relate to actual clinical use?
  - Consider length of time device used
  - Consider a range of clinically relevant pathogens
- Comparing modified antimicrobial N95 Respirators with unmodified Respirators



## Safety Assessment

Depends on:

- Type of Antimicrobial Agent and its ability to leach off/gas off from the respirator?
- Concentration of the Antimicrobial Agent?
- Location of the Antimicrobial Agent (outer, Inner or Middle layers)?



## Safety Issues

- Will the agent gas-off/leach-off/physically detach from the respirator. If so, does antimicrobial agent releases from the respirator? Where could the agent go? Could it reach the oral, nasal or ocular areas?



# Questions/Comments?