


Personal Protective Equipment Regulated by FDA

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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 and effective
- 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 General Controls

Mostly exempt from 510(k)

Class II Intermediate Risk General Controls & Special Controls & Premarket

Notification 510(k)

Class III High Risk General Controls and Premarket Approval (PMA)

FDA Regulation of Medical Devices

General Controls

- Premarket Notification Submission (unless exempt) or Premarket Approval
- 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 as safe and as effective or ***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

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Class II Devices

Subject to Premarket Notification Submission
[510(k)]

- Surgical Masks and N95 Surgical Respirators
- Surgical Gowns
- Isolation Gowns are Class I devices but become Class II devices if additional claims are made, such as barrier function claims

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Class I Non-Exempt Devices Need 510(k)

- Examination Gloves
- Surgeons' Gloves

Class I Exempt Devices No 510(k)

- Eye Protection
- Other Surgical Apparel

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510(k) Submissions Gloves/Gowns/Masks

- Single Use/Disposable Gloves/Masks
- Single Use or Reusable Gowns
- Biocompatibility Testing Recommended for All –
Gloves/Gowns/Masks
- Latex Caution Statement Required if natural
rubber latex is a device component

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510(k) Submissions Gloves/Gowns/Masks

- Sterilized Surgeon's Gloves
- Non-Sterile Examination Gloves/Masks
- Sold both Sterile and Non-Sterile - Surgical Gowns. If sold non-sterile, manufacturer must provide validated sterilization instructions.

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- Recognized Consensus Standards and FDA Guidance documents facilitate the premarket review process for Class II medical devices.
- Conformance with Recognized Consensus Standards can provide reasonable assurance of safety and effectiveness for many aspects of medical device evaluation.
- Standards produce voluntary consensus among industry, health care device users and FDA.
- Standards are updated as technology and experience advance.

Standards for Performance Testing of a Surgical Mask

Filtration Efficiency

➤ Particulate Filtration ASTM F 1215:1989

➤ Bacterial Filtration

ASTM F 2101:2001

Modified Greene & Vesley Method J.

Bacteriol 1962 83:663-667

Bacterial Penetration – Mil-369454C Mil Spec

6/12/75

Standards for Performance Testing of a Surgical Mask

- Fluid Resistance ASTM F 1862:2000a
- Differential Pressure Mil – M – 36945C
4.4.1.1.1 Method 1 Mil Specs 6/12/75
- Flammability
 - 16 CFR 1610 (CPSC CS-191-53)
 - UL 2154
 - NFPA Standard 702 1980 (Withdrawn by NFPA)

Note Biocompatibility Testing per ISO 10993 Part 10

Standards for Performance Testing of an N95 Surgical Respirator

- NIOSH Certification
- Fluid Resistance ASTM F 1862
- Flammability Testing
 - 16 CFR 1610 (CPSC CS-191-53)
 - UL 2154
 - NFPA Standard 702 1980 (Withdrawn by NFPA)

Note: Biocompatibility Testing ISO 10993 Part 10

Standards for Performance Testing of Surgical Gowns

Barrier Performance ANSI/AAMI PB70:2003

4 Levels of Performance at an AQL of 4%

1. AATCC 42:2000 $\leq 4.5\text{gm}$

2. AATCC 42:2000 $\leq 1.0\text{gm}$

AATCC 127:1998 $\geq 20\text{cm}$

3. AATCC 42:2000 $\leq 1.0\text{gm}$

AATCC 127:1998 $\geq 50\text{cm}$

4. ASTM F 1671:2003 PASS

Standards for Performance Testing of Surgical Gowns

Non-Barrier Property Performance

Grab Tensile Strength ASTM D5034:1995

Snag Resistance ASTM D5587:1996

ASTM D2582:2000

Linting IST 160.1:1995

Heat Loss ASTM F1868:1998 Part C

Water Vapor Transmission ASTM E96:2000

Standards for Performance Testing of Surgical Gowns

Flammability 16 CFR Part 10(CPSC CS-191-53)

UL 2154

NFPA 702 1980 (Withdrawn)

Sterilization Method and Validation

Reusable Laundering Instructions

Recommended Number of Uses

Method for Tracking Number of Uses

Standards for Performance Testing of Surgical Gowns

Biocompatibility Testing ISO 10993 Part 10

Skin Irritation

Skin Sensitization



Standards for Performance Testing of Medical Gloves

Examination Gloves

Surgeons' Gloves

Specialty Gloves

Chemotherapy Label Claim

Radiation Attenuating Surgeons' Gloves

Accessories Liners/Undergloves, Finger Cots,

Surgeons' Gloving Cream, Leak Detectors

Absorbable Dusting Powder is a Class III Device

Standards for Performance Testing of Medical Gloves

Glove Specifications

- Overall Length mm
- Width mm
- Palm Thickness mm
- Tensile Strength Before Aging Mpa Minimum
After Aging Mpa Minimum
- Ultimate Elongation Before Aging % Minimum
After Aging % Minimum
- Pinhole AQL

Standards for Performance Testing of Medical Gloves

Glove Specifications

- Latex Gloves ASTM D 3578:2005
- Vinyl Gloves ASTM D 5250:2000e4
- Synthetic Polymer Gloves ASTM D3578:2005
ASTM D6977:2004
- Nitrile Gloves ASTM D6319:2000ae3
- Surgeons' Gloves ASTM D 3577:2001ae2

Standards for Performance Testing of Medical Gloves

Biocompatibility Testing ISO 10993 Part 10

Skin Irritation

Dermal Sensitization

Reduced Risk of Sensitization (Modified Draize
Test on a minimum of 200 human subjects)

Testing is performed on the final finished product,
including color and flavor additives

Standards for Performance Testing of Medical Gloves

All medical gloves containing natural rubber latex must be labeled in bold print as required by 21 CFR 800.43(d).

“Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions”.

Standards for Performance Testing of Medical Gloves

Attribute Labeling

- Powder-Free 2mg or less of residual powder
ASTM D 6124:2001
- Reduced Protein Level 50ugm/dm² or less of extractable protein
ASTM D 5712:2005e1 (Lowry Test)
ASTM D 6499:2003
ASTM D 3578:2005 for real time/accelerated aging

Standards for Performance Testing of Medical Gloves

Resistance of Medical Gloves to Permeation
by Chemotherapy Drugs

ASTM D6978:2005



Standards for Performance Testing of Medical Gloves

Sterilization of Medical Gloves

- Sterilization Method and Validation
- Gloves should be tested to ensure that they meet the respective listed glove specifications AFTER sterilization
- If gloves are to be sterilized after marketing, the manufacturer should provide validated directions for sterilization







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21 CFR 878.4040 Surgical Apparel

Devices intended to be worn by operating room personnel during surgical procedures to protect both the patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate materials

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21 CFR 878.4460 Surgeon's Glove

A device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

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21 CFR 880.6250 Patient Examination Glove

A disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner



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Class I Non-Exempt Devices

Certain Class I devices are NOT exempt
from Premarket Notification Submission

- Surgeon's Gloves
- Examination Gloves

Personal Protective Equipment (PPE) Regulated by FDA

Gloves	Examination and Surgical
Masks	Surgical Masks and Surgical N95 Respirators
Gowns	Surgical Gowns and Isolation Gowns
Eye Protection	Goggles and Face Shields
Other Surgical Apparel	Surgical Caps, Hoods, Shoes, Shoe Covers and Boots

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510(k) Premarket Notification Submission

FDA recommends that the manufacturer conduct an analysis of the risks associated with the use of his device and identify the measures taken to mitigate these risks. These measures are identified in performance testing. FDA reviews the submission to determine if the device is “substantially equivalent” to its legally marketed predicate device.

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- Conformance with Recognized Consensus Standards can provide reasonable assurance of safety and/or effectiveness for many aspects of medical device evaluation.
- Standards are updated as technology and experience advance
- Standards provide consistency in performance expectations and in submission review.