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
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 

\textit{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.
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 \(\leq 4.5\)gm
2. AATCC 42:2000 \(\leq 1.0\)gm
3. AATCC 127:1998 \(\geq 20\)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
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 5250:2000
- Synthetic Polymer Gloves   ASTM D3578:2005
- Nitrile Gloves   ASTM D6319:2000
- Surgeons’ Gloves   ASTM D 3577:2001
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.