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Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care

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Scope

- **Limited to gowns making liquid barrier protection claims and intended for use in health care settings.**
- **Minimal or Low Barrier protection**

  ANSI/AAMI PB70 Level l protection or equivalent; or

  ANSI/AAMI PB70 Level2 protection or equivalent.
- **Moderate or High Barrier protection**

  ANSI/AAMI PB70 Level 3 protection or equivalent; or

  ANSI/AAMI PB70 Level 4 protection or equivalent

Device Classification

- **21 CFR 878.4040 Surgical apparel.**

(a) Identification. 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. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) Classification. (1) Class II (special controls) for surgical gowns and surgical masks.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

Class I Exempt Gown

NOT a "surgical gown" if all of the following factors apply:

- **it is labeled as a gown other than a surgical gown (e.g., isolation gown);**
- **it is not described in its labeling as a surgical gown; and**
- **if it has statements relating to barrier protection, such statements are for only minimal or low barrier protection.**

Class II Gown

"Surgical Gown" if <u>any</u> of following applies:

- **it is labeled as such;**
- **it is described as such in its labeling;**
- **it has statements relating to moderate or high level barrier protection; and/or**
- **it has statements that it is intended for use during sterile procedures.**

Class II Gown

Subject to Premarket Notification Submission [510(k)]

- Surgical Gowns
- Surgical Isolation Gowns
  - Isolation Gowns are Class I devices but become Class II devices if additional claims are made, such as moderate or high barrier function claims
  - Isolation Gowns with such barrier function claims are defined as “surgical isolation gowns”

FDA Premarket Review of Gowns

- **1993 guidance document for surgical gowns**
- **2015 guidance document for surgical gowns**
- **Performance Testing**
  - Resist blood and liquid penetration - ANSI/AAMI PB70
- **Safety Testing**
  - Biocompatibility
  - Sterilization method and validation (surgical only)
  - Other properties: physical strength, comfort, heat dissipation, vapor transmission, linting, flammability, dyes

FDA Premarket Review of Gowns

- **Labeling**
  - Representative engineering drawing(s), schematics, illustrations and/or figures of the gown that are clear, legible, labeled with the barrier protection levels of the gown, and include dimensions and the location of the critical and non-critical zones.
  - Identifies the level of liquid barrier protection per ANSI/AAMI PB70.
  - Direction(s) for use and indication(s) for use.

Premarket Notification (510(k)) for Surgical Gowns and "Surgical Isolation Gowns"

- **Evidence that the gown complies with the claimed barrier performance criteria of ANSI/AAMI PB70, or equivalent standard.**
- **Performance test data to demonstrate that the gown is an effective barrier in accordance with ANSI/AAMI PB70.**
- **Clear description of the device design.**
- **Identify all models, including dimensions, manufacturing specifications and tolerances, for each device design.**

Premarket Notification (510(k)) for Surgical Gowns and "Surgical Isolation Gowns"

- **Representative engineering drawing(s), schematics, illustrations and/or figures of the gown labeled with the barrier protection levels, dimensions and the location of the critical and non-critical zones.**
- **Sample labeling that clearly identifies the level of liquid barrier protection per ANSI/AAMI PB70.**
- **Sample labeling that includes the direction(s) for use and indication(s) for use.**

Premarket Notification (510(k)) for Surgical Gowns and "Surgical Isolation Gowns"

- **List all components of the device and identify if each component is intended for single use only, single patient reusable, or multiple patient use.**
- **Provide a comparison table of the device and the predicate device to support substantial equivalence.**
- **Provide sterilization information as described in the guidance, Updated 510(k) Sterility Review Guidance K90-1 - Final Guidance for Industry and FDA.**

Premarket Notification (510(k)) for Surgical Gowns and "Surgical Isolation Gowns"

- **For both single use and reusable gowns, barrier performance testing should be completed on the final, finished, pre-shipment gown, at the end of the stated shelf life of the gown.**
- **If the gown is intended to be reusable, barrier performance testing should also be performed at the end of the labeled use-life (maximum reprocessing cycles).**

Standards for Performance Testing of Surgical Gowns

Barrier Performance ANSI/AAMI PB70:2003

- 4 Levels of Performance at an AQL of 4%

Level 1	AATCC 42:2000	</= 4.5gm
Level 2	AATCC 42:2000 AATCC 127:1998	</= 1.0gm >/= 20cm
Level 3	AATCC 42:2000 AATCC 127:1998	</= 1.0gm >/=50cm
Level 4	ASTM F 1671:2012	PASS

Standards for Performance Testing of Surgical Gowns

- **Non-Barrier Property Performance Testing**

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 E96:20

Standards for Performance Testing of Surgical Gowns

- **Non-Barrier Property Performance Testing cont.**

Flammability	**16 CFR Part 10(CPSC CS-191-53)** **UL 2154** **NFPA 702 1980 (Withdrawn)**
Sterilization	**Sterilization Method and Validation**
Reusable Laundering Instructions	**Recommended Number of Uses** **Method for Tracking Number of Uses**

Standards for Performance Testing of Surgical Gowns

- **Performance Testing**

Biocompatibility Testing	**ISO 10993 Part 10** **Skin Irritation** **Skin Sensitization**

FDA Expectations for Manufacturers

Manufacturers proposing to market or those currently marketing Class II gowns as described in this guidance should:

- **Submit a 510(k) for the gown to the Agency within 60 days of publication of the final guidance**
- **Have a 510(k) submission for the gown accepted by the Agency for review within 75 days of publication of the final guidance**
- **Obtain 510(k) clearance for the gown within 180 days of publication of the final guidance.**

Relevant FDA Guidance Documents

- **Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings**

  http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm452804.pdf

- **Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes**

  http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081305.pdf

Relevant FDA Guidance Documents

- **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm072783.htm
- **Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s**
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm
- **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff.**
  http://www.fda.gov/downloads/MedicalDevices/…/UCM284443.pdf

FDA Recognized Standards

- ASTM F2407

  Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities

- ASTM F1670

  Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

- AAMI/ANSI PB70

  Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

FDA Recognized Standards

- ASTM F1671

  Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

- AAMI ST65

  Processing of reusable surgical textiles for use in health care facilities

Questions?

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