Welcome to today’s FDA/CDRH Webinar

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510(k) Review for Surgical Mask

Office of Health Technology 4: Surgical and Infection Control Devices
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration (FDA)
Surgical Mask: 510(k) Submission General Contents

• 21 CFR §878.4040(b), Product Code FXX
  – 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 the guidance document include masks that are labeled as a surgical, laser, isolation, dental or medical procedure masks.

• Submission Contents
  – Device Description
  – Subject & Predicate Device Comparison
  – Labeling
Safety Assessment

• Biocompatibility
  – Surface Contacting, Prolonged Duration
  – Endpoints to Assess
    • Cytotoxicity (ISO 10993-5)
    • Irritation/Intra-cutaneous reactivity (ISO 10993-10)
    • Sensitization (ISO 10993-10)
Performance Testing

• Fluid Resistance
• Filtration Efficiency
  – Bacterial Filtration Efficiency
  – Particulate Filtration Efficiency
• Differential Pressure (Delta-P) Test
• Flammability Testing
Resources

- **Surgical Masks - Premarket Notification [510(k)] Submissions**: Guidance for Industry and FDA Staff
  [https://www.fda.gov/media/71660/download](https://www.fda.gov/media/71660/download)

  [https://www.fda.gov/media/85865/download](https://www.fda.gov/media/85865/download)

- **Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile**: Guidance for Industry and Food and Drug Administration Staff
  [https://www.fda.gov/media/74445/download](https://www.fda.gov/media/74445/download)

- **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]:** Guidance for Industry and Food and Drug Administration Staff
  [https://www.fda.gov/media/82395/download](https://www.fda.gov/media/82395/download)

- **510(k) Submission Process Web Page**
  [https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process](https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-process)
Resources

- **ASTM F2100-19** Standard Specification for Performance of Materials Used in Medical Face Masks

- **ASTM F1862** Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

- **ASTM F2101-19** Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

- **ISO 10993-1** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

- **ISO 10993-5** Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

- **ISO 10993-10** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- **ISO 2859-1** Sampling procedures for inspection attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection [Including: Technical Corrigendum 1 (2001), Amendment 1(2011)]

- **ANSI ASQ Z1.4-2003** Sampling Procedures and Tables for Inspection by Attributes
Webinar Resources

Slide Presentation, Transcript and Webinar Recording will be available at:
www.fda.gov/training/cdrhlearn
Under Heading: Specialty Technical Topics and Sub-heading Personal Protective Equipment (PPE)

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