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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>
- **Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”:** Guidance for Industry and Food and Drug Administration Staff
<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>
- **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>
- **510(k) Submission Process** Web Page
<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
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=39911
- **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)
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=36979
- **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
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=39935
- **ISO 10993-1** Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=38569
- **ISO 10993-5** Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=36819
- **ISO 10993-10** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=36826
- **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)]
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=32318
- **ANSI ASQ Z1.4-2003** Sampling Procedures and Tables for Inspection by Attributes
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=32711

Webinar Resources



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