



FDA Regulatory Process for Premarket [510(k)] Submission: Surgical N95 Respirators Fluid Barrier Performance



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510(k) Review Process N95 Respirator

Performance criteria

- **Fluid Resistance**
- Filtration Efficiency
 - Particle Filtration Efficiency (NIOSH Certification)
 - Bacterial Filtration Efficiency
 - Viral Filtration Efficiency (optional)
- Flammability
- Differential Pressure (NIOSH Certification)
- Biocompatibility



Fluid Barrier Performance is an expected element of Surgical N95 Respirators per 21 CFR 878.4040.

Fluid Barrier Performance for Surgical Masks and Respirators are based on Resistance to Synthetic Blood

- FDA recognized Consensus Standards
 - ASTM F2100 (2011): Standard Specification for Performance of Materials Used in Medical Face Masks
 - ASTM F1862 (2013): Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

ASTM F1862 contains test methodology for fluid barrier performance.

- Small volume of high velocity stream of synthetic blood.
 - Controlled fluid composition, volume, distance & velocity
 - Pass/Fail Test criteria
 - Any evidence of blood presentation = fail
 - Tested over a range of pressure conditions.
 - Methodology to ensure consistent test conditions.

FDA current expectations are fluid barrier testing against simulated blood penetration challenge.

- Final, finished device
- ASTM F1862 (2013) is FDA-recognized consensus standard
 - Voluntary
 - Alternate, equivalent test methods may be acceptable.
- Performance claims and materials of construction may result in requirement of additional challenge conditions.

FDA current expectations are fluid barrier testing against simulated blood penetration challenge.

- Established regulatory history for blood penetration challenges.
- Barrier performance for N95 respirators
 - Trade-off: Fluid resistance vs. breathability
 - Use conditions may drive increased performance expectations.



Questions/Discussion