

K965043

P. 1

510(k) Summary

MAR 10 1997

MANUFACTURER: 3M Health Care
3M Center
St. Paul, MN 55144-1000

REGULATORY AFFAIRS CONTACT: Karen C. Maass
Regulatory Affairs Specialist
3M Medical Markets Group
3M Center, Bldg. 275-3E-08
St. Paul, MN 551441-1000

TELEPHONE: (612) 736-1031

DATE SUMMARY PREPARED: October 9, 1996

DEVICE TRADE NAME: 3M 1830 Fluid Block Anti-Fog Tie-on Surgical Mask,
3M 1830FS Fluid Block Anti-Fog Tie-on Surgical
Mask with Face Shield

COMMON OR USUAL NAME: Surgical Mask

CLASSIFICATION: Surgical Apparel, Class II, 21 CFR 878.4040

PREDICATE DEVICES: 3M 1818 Tie-on Surgical Mask and 3M 1818FS Tie-On Surgical Mask with Face Shield (K940707).
Tecnol FluidShield(R) Surgical Masks (K913043).

DEVICE DESCRIPTION The 1830/1830FS is a flat, pleated, tie-on mask consisting of inner and outer cover webs with two different filter webs sandwiched in between. It covers the nose and mouth of the wearer, and is held in place by tie strings and a malleable plastic coated wire nose piece.

INTENDED USE: The product is intended for use in infection control practices to minimize contamination caused by exhaled microorganisms. In addition, the device is intended to reduce potential exposure of the wearer to blood and body fluids.

**SUBSTANTIAL
EQUIVALENCE:**

The 3M 1830/1830FS masks are the same product as the 3M Surgical Masks with Face Shield (K940707), with an additional "fluid block" layer to improve the masks fluid resistance. The following characteristics of the 3M 1830/1830FS mask indicate this device is substantially equivalent to the predicate devices listed above.

- * Intended use
- * Bacterial filtration efficiency
- * Fluid resistance
- * Anti-Fog coated face shield (1830FS only)
- * Anti-fog strip incorporated in the mask design to reduce fogging of glasses
- * Soft, non-irritating inner surface
- * Flat, pleated, tie-on design
- * Special fluid resistant layer
- * Target population

**TESTING
SUMMARY:**

Standard biocompatibility testing in animals and humans (including Cytotoxicity-Agar-Overlay, Primary Skin Irritation, Ocular Irritation, Human Draize Sensitization, and 21-Day Cumulative Irritation) on the product and/or its components indicate that the 1830/1830FS mask is non-irritating and hypoallergenic and safe for its intended use.

The following tests support the 1830/1830FS mask as acceptable for its intended use:

Mod. Greene & Vesley	>99% BFE
0.1 Micron Latex Particle Challenge	>95% PFE
Fluid Resistance (Cup Test)	Resists a liquid volume > 65 ml for 120 hr.
Fluid Resistance (Nelson Test)	Resists liquid pressures under various conditions, i.e. 2cc synthetic blood at 120 mm Hg (2.3 psi)/1.5 inches/1 assault, and 2.3 cc synthetic blood at 300 mm Hg (5.8 psi)/18 inches/5 assaults.

K985043
P-3

**TESTING
SUMMARY (continued):**

Differential Pressure (Delta P) 1818/1818FS <
1830/1830FS < TecnoI
FluidShield #47123-070 at
a face velocity of 20 ft/min.
and airflow of 62 lpm.
Delta P = 2.4, 4.2 and 5.0
respectively.

Anti-Reflective Test Anti-reflective coating
reduces reflections on
shield by > 80%.