K955382

Attachment 3
510(k) Summary

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(1)	Submitter:	Minnesota Mining and Manufacturing Company (3M) Occupational Health and Environmental Safety Division 3M Center, Building 260-3A-07 St. Paul, Minnesota 55144-1000
	Contact Person:	Dorothea von Busch
	Phone Number:	612-737-8838
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(2)	Device Name/ Trade Name:	3M™ Model 1860 Health Care N95 Particulate Respirator and Surgical Mask
	Common Name:	Surgical Mask Also sometimes referred to as a Particulate Respirator
	Classification Name:	Surgical Apparel, as described in 21 CFR 878.4040
(3)	Predicate Device(s):	3M Model 1812 surgical mask; Tecnol DMR2010 respirator and Lazer™ Surgical Mask
(4)	Device Description:	The 3M 1860 is a molded, cup-shaped respirator, consisting of a semi-rigid innershell, filter media, and a coverweb. It covers the nose and mouth of the wearer, and is held snugly in place with two synthetic elastic headbands, conforming to the curvature of the wearer's nose with a malleable aluminum noseclip.
(5)	Intended Use:	- Meets the CDC guidelines for TB exposure control - Has a filter efficiency level of 95% or greater against particulate aerosols free of oil (Type N95 respirator) - Minimizes wearer exposure to certain airborne particles in a size range of 0.1 to 10.0 microns, such as those generated by electrocautery, laser, and other powered medical instruments - Designed to be fluid resistant to splash and spatter of blood and body fluids and other potentially hazardous biomaterials - Provides greater than 99% Bacterial Filtration Efficiency* to exhaled wearer generated microorganisms (*as determined by the modified Greene and Vesley test method)
(6)	Technological Characteristics Comparison:	No new technological characteristics are used in the 1860

(7)	Performance Data Summary:	**Filtration Efficiency:** subject device samples met the NIOSH required sodium chloride test, with particles having a count median diameter of 0.055 to 0.095 microns, and an aerodynamic diameter of 0.3 microns; at no time can the filtration efficiency drop below 95%. **Fluid Resistance:** subject device samples were challenged with 100 ml ±1 ml for up to 24 hours; no fluid penetration was observed. **Multiple Sized Particles Penetration Test:** subject device samples were challenged with particles of multiple sizes, having an aerodynamic diameter range of 0.1μm to 10.1μm; the filter efficiency level was greater than 99%. **Bacterial Filtration Efficiency:** subject device samples were tested using the modified Greene and Vesley procedure; filtration efficiency was greater than 99% **Face Fit:** subject device samples were tested using a qualitative fit test; face seal leakage was less than 10% **Ease of Breathing:** subject device samples met the requirements of the NIOSH airflow resistance test which requires initial resistance (inhalation) to be less than 35mmH_2O. **CONCLUSION:** the results of these nonclinical tests, when compared with data available and/or claims made on the predicate devices, demonstrate that the subject device is as safe and effective as the predicate devices. and performs as well as the predicate devices.