

510(K) Summary

K960778

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Submitter

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Trade Name:

Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask
Model 2735

Common Name:

Healthcare Particulate Respirator and Surgical Mask

Classification

Device Class - Class II
CFR Section - 21 CFR 878.4040

Substantial Equivalency:

The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is found to be substantially equivalent to the Gerson Isolair SMF 510 (k) number K922507. The product is manufactured in the same manner but utilizes more efficient filter media.

510(K) Summary (Continued)

Description:

The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is constructed from a white nonwoven material used in the inner and outer shell. The polypropylene melt blown filter media is layered between the inner and outer shell. The headband is made of rubber stapled to the mask. The inside nosepiece utilizes a closed cell foam and the outside nosepiece which conforms to the nose is made of aluminum.

The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is approved by NIOSH as per 42 CFR 84. The certification number assigned is TC-84A-160 for a type N95 Particulate Respirator. The Type N95 must meet the prescribed test criteria which specifies the use of 0.3 micron diameter challenge and requiring a 95% efficiency. This mask is also fluid resistant as per (ASTM D583 65 Method) and is resistant to synthetic blood as per Protocol number 9602202-01 conducted by Nelson Laboratories. Breathing resistance was tested as per NIOSH 30 CFR11 section 11.140-9.

Intended Use:

The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

This device also meets CDC Guidelines for TB Exposure Control.

Limitations:

This product does not eliminate the wearer from any risk of contracting any type of disease or infection. The mask should be changed immediately if contaminated with blood or body fluids.

510(K) Summary (Continued)

Comparison of Predicate Device

The outside cover stock color of the previously cleared device is blue. The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is white. The headband color of the cleared device is white and the Isolair APR Type N95 is green.

The Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 incorporates a highly efficient filter media and is 95% efficient against a .3 micron particulate which was scientifically established as the most penetrating particle size. The legally marketed device previously cleared 510 (k) K922507 is manufactured from similar materials, but does not have the high efficiency characteristics as the new Isolair APR Type N95

Performance Tests:

This product was tested and certified by NIOSH as an approved N95 respirator. It meets all the requirements prescribed in 42 CFR 84 and is assigned TC-84A-160.

Tests Performed	Laboratory
1. Department of Health and Human Services 42 CFR 84 Type N95 Requirements	NIOSH
2. Resistance to Liquid (Synthetic Blood Penetration Resistance) Protocol No. 9602202-01	Nelson Laboratories
3. Breathing Resistance 30 CFR 11	NIOSH
4. Fluid Resistance (ASTMD583-65 Method 1)	Gerson
5. Filtration Efficiency NIOSH 42 CFR 11	NIOSH
6. Primary Skin Irritation	Gerson
7. FHSA Primary Dermal Irritation	Nelson Laboratories

510(K) Summary (Continued)

Conclusion:

Since the basic construction is used in the cleared device as in the new device except for incorporation of a highly efficient filter media tested and approved by NIOSH, the Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735 is substantially equivalent to the Gerson SMF product.

Safety/Effectiveness

The device has a filtration much greater than the previously cleared Gerson SMF Surgical Mask Respirator. It is NIOSH approved and meets the CDC guidelines for TB Exposure Control.