

**RACAL HEALTH & SAFETY INC.
PREMARKET SUBMISSION**

**RACAL N95 RESPIRATOR AND SURGICAL MASK
510(K) K964723**

510(k) SUMMARY - K96 4723

FEB - 7 1997

RACAL N95 RESPIRATOR & SURGICAL MASK

January 29, 1997

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), Premarket Notification, was in accordance with 21 CFR 807.87.

1. **Submitter of 510(k):**

Company Name: Racal Health & Safety Inc.
7305 Executive Way
Frederick, Maryland
U.S.A. 21704-8368

Contact Person (U.S.A.): Mr. J. Randall Hoggle
Telephone: (301)695-8200
Fax: (301)695-4413

Contact Person (Canada): John Campbell
Telephone: (613)345-0111
Fax: (613)345-2639

2. **Name of Device**

Trade/Proprietary Name: RACAL N95 RESPIRATOR AND SURGICAL MASK

Common/Usual Name: Masks, Surgical

Classification Name: 21 CFR 878.4040 "Surgical Apparel", Class II

3. **Legally Marketed Predicate Devices**

RACAL N95 RESPIRATOR AND SURGICAL MASK is substantially equivalent to many legally marketed Surgical masks, including those listed in Table I below.

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**TABLE 1
COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
PREDICATE DEVICES AND DELTA N95 RESPIRATOR AND SURGICAL MASK**

Manufacturers	Racal Health & Safety	3M	Louis M Gerson
Device	RACAL N95 Respirators	Model 1860 Health Care Respirators	Isolair APR Type N95 Respirators
510(k) Number	K964723	K955382	K960778
Standards Met	Performance Code of Federal Regulations, Title 42 Part 84 for N95-class of Respiratory Protective Devices Meets CDC guidelines for preventing transmission of Mycobacterium tuberculosis	Performance Code of Federal Regulations, Title 42, Part 84 for N95-class of Respiratory Protective Devices Meets CDC guidelines for preventing transmission of Mycobacterium tuberculosis	Performance Code of Federal Regulations, Title 42, Part 84 for N95 - class of Respiratory Protective Devices Meets CDC guidelines for preventing transmission of Mycobacterium tuberculosis
NIOSH Approval Number	TC- 84A-008	TC - 84A- 006	TC-84A-160
Device Description	<ul style="list-style-type: none"> • N95 Class particulate Respirator • Multi-Layer Filtering media • Fluid resistant barrier • Wire nose clip • Foam nose piece inside mask • Elastic Headband • Peach colored 	<ul style="list-style-type: none"> • N95 Class particulate Respirator • Multi-Layer Filtering media • Fluid resistant barrier • Wire nose clip • Foam nose piece inside mask • Elastic Headband • Blue colored 	<ul style="list-style-type: none"> • N95 Class particulate Respirator • Multi-Layer Filtering media • Fluid resistant barrier • Wire nose clip • Foam nose piece inside mask • Elastic Headband • Blue-green colored
Intended Use	Respiratory Protection of Health Care workers	Respiratory Protection of Health Care of workers	Respiratory Protection of Health Care workers

4. Device Description

RACAL N95 RESPIRATOR AND SURGICAL MASK is indicated for respiratory protective device. This disposable Surgical mask is a one-piece, light weight half mask with filter material forming the mask. The component includes an inner scrim layer, netting material forming the mask. The component includes an inner scrim layer, netting layer, meltblown protection layer, outer scrim layer and elastic band. RACAL

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N95 RESPIRATOR AND SURGICAL MASK is NIOSH approved (Approval #TC-84A-0008) and has a filtration efficiency level of 95% and is effective against particulate aerosols free of oil. RACAL N95 RESPIRATOR AND SURGICAL MASK is available in four sizes, extra small, small, medium and large. The nose clip and elastic headband ensures effective face to mask seal. Based on the information provided, RACAL N95 RESPIRATOR AND SURGICAL MASK is substantially equivalent to legally marketed predicate devices.

5. Indications For Use

The Racal N95 Respirator and Surgical Mask will be used for the protection of the health care practitioner from blood and body fluids and particulates and to meet the NIOSH / CDC TB Prevention Guidelines.