

K061375

510 (k) Summary

Submitter:

Louis M. Gerson Co., Inc.
15 Sproat Street
Middleboro, MA 02346

NOV 17 2006

Contact:

Robert A. Brunell
Regulatory Affairs Manager
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Date: November 15, 2006

Trade Name:

1730 N95 Particulate Respirator

Common Name:

1730 N95 Particulate Respirator

Classification:

Device Class – Class II
CFR Section – 21 CFR 878.4040

Substantial Equivalency:

The 1730 N95 Particulate Respirator and Surgical Mask is found to be substantially equivalent to the Gerson Isolair APR Type N95 Healthcare Particulate Respirator and Surgical Mask Model 2735. The product is manufactured in the same manner, with the exception of welded elastic headbands and open celled foam as opposed to stapled rubber headbands with a closed cell foam. It is a fluid resistant, disposable single use mask.

Description:

The 1730 N95 Particulate Respirator and Surgical Mask is constructed from a white nonwoven material used for the inner and outer shell. The polypropylene meltblown filter media is layered between the inner and outer shell. The headband is made of elastic and welded to the mask. The inside nosepiece is made of an open celled foam and the outside nosepiece, which conforms to the nose, is made of aluminum.

The 1730 N95 Particulate Respirator is approved by NIOSH as per 42 CFR 84. The certification number assigned is TC-84A-160 for a type N95 Particulate Respirator. The N95 must meet the prescribed test criteria of a 0.3 micron diameter challenge and requiring a 95% efficiency. This mask is also fluid resistant as per the ASTM D583-65 Method 1 and is resistant to synthetic blood as per protocol number 9602202-01 conducted by Nelson Laboratories. Breathing resistance was tested as per 42 CFR 84.

Intended Use:

The 1730 N95 Particulate Respirator and Surgical Mask 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 matter.

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. It is a disposable single use mask.

Comparison of Predicate Device:

The outside cover stock of the previously cleared device is white, as is the 1730 N95 Particulate Respirator. The 1730 has welded elastic headbands similar to the 2735's stapled rubber headbands. The 1730 uses an open celled foam comparable to the 2735's closed cell foam.

The 1730 N95 Particulate Respirator and Surgical Mask incorporates a highly efficient filter media and is 95% efficient against a 0.3 micron particulate size, which was scientifically established as the most penetrating particle size. The previously cleared device had the same efficiency.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Brunell
Manager of Regulatory Affairs
Louis M. Gerson Company, Incorporated
15 Sproat Street
Middleboro, Massachusetts 02346

NOV 17 2006

Re: K061375

Trade/Device Name: Gerson 1730 Type N95 Particulate Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: September 27, 2006
Received: November 7, 2006

Dear Mr. Brunell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

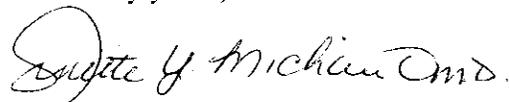
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061375

Device Name: Gerson 1730 Type N95 Particulate Respirator

Indication For Use:

The Gerson 1730 N95 Particulate Respirator is intended to be worn by operating room personnel during healthcare procedures to protect both the patient and healthcare professionals from the transfer of microorganisms, bodily fluids and particulate material.

This device also meets CDC guidelines for TB exposure.

Subject device is also a surgical mask and is single use / disposable.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Print Sign-Off)
Chief of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K061375