

Tecno! Medical Products, Inc.
510(k) Premarket Notification
PFR95™ Particulate Filter Respirator and Surgical Mask

K974068

DEC 22 1997

Tab H
1 of 2**510(k) SUMMARY**

- (1) **Submitter:** Tecno! Medical Products, Inc.
7201 Industrial Park Blvd.
Fort Worth, TX 76180
- Prepared By:** Ruth L. Jones
- Date Submitted:** October 24, 1997
- (2) **Device Name/
Trade Name:** Tecno! PFR95™ Particulate Filter 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:** Gerson Isolair APR Type N95 Model 2735 Respirator
and Surgical Mask
- (4) **Device Description:** Respirator consisting of nonwoven inter facing, filter
media(s), and an outer facing. It covers the nose and mouth
of the wearer, and is held in place with two synthetic elastic
headbands, conforming to the curvature of the wearer's
nose with a malleable nosepiece.
- (5) **Intended Use:** Meets the CDC guidelines for TB exposure control.
Has a filter efficiency level of 95% against solid particulate
aerosols free of oil (NIOSH Type N95 respirator).
Designed to be fluid resistant to splash and splatter of blood
and body fluids.
- (6) **Technological
Characteristics
Comparison:** No new technological characteristics are used in the
PFR95™ mask.

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- (7) Performance Data:
- Filtration Efficiency:** Subject device samples met the NIOSH required sodium chloride test with 0.3 micron particles. At no time can the filtration efficiency drop below 95%.
 - Fluid Resistance:** Subject device samples were challenged with 2cc of synthetic blood at a speed simulating release of blood from an artery.
 - Face Fit:** Subject device samples were tested using a qualitative fit test.
 - Ease of Breathing:** Subject device samples met the requirements of the NIOSH airflow resistance test which requires initial resistance (inhalation) to be less than 35mm H₂O.
 - Biocompatibility:** Subject device meets the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

CONCLUSION: The results of these nonclinical tests, when compared with data available and/or claims made on the predicate device, demonstrate that the subject device is as safe and effective as the predicate device, and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Ms. Ruth L. Jones
Director of Regulatory Affairs
Tecnol Medical Products, Incorporated
7201 Industrial Park Boulevard
Fort Worth, Texas 76180

Re: K974068
Trade Name: PFR95™ Particulate Filter Respirator and
Surgical Mask Regular Size
Regulatory Class: II
Product Code: MSH
Dated: October 24, 1997
Received: October 28, 1997

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

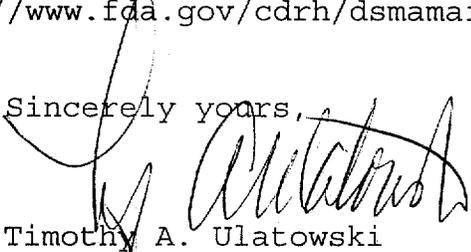
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tecnol Medical Products, Inc.
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Intended Use

510(k) Number: K974068

Device Name: PFR95™ Particulate Filter Respirator and Surgical Mask
Type N95

Indications for Use:

The PFR95™ Particulate Filter Respirator and Surgical Masks are intended for use by operating room personnel and other health care workers to protect both the patients and the health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *George A. Miller, MD*
Division of Dental, Infection Control, *Chiu S. Tin, Ph.D.*
and General Hospital Devices
510(k) Number K974068

Prescription Use _____ OR Over-the-Counter Use

(Per 21 CFR 801.109)