DERMAGRIP POWDER FREE NR LATEX EXAMINATION GLOVES, NON-STERILE

510(k) PREMARKET NOTIFICATION LETTER FROM THE FOOD AND DRUG ADMINISTRATION (FDA), UNITED STATES OF AMERICA

Your Partner In Protection™

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 1996

Dr. Ong Ghee Chee
Quality Assurance Manager
Wembley Rubber Products (M) Sdn Bhd
Lot 1, Jalan 3
Kawasan Perusahaan Bandar Baru
Salak Tinggi, 43900 Sepang,
Selangor, Malaysia

Re: K953590
Trade Name: Comfit Powder-Free Latex Examination Gloves, Hypoallergenic, Protein Content Labeling
Regulatory Class: I
Product Code: LYY
Dated: June 6, 1996
Received: June 10, 1996

Dear Dr. Ong Ghee Chee:

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 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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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.

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MARKETING
File

Please also be advised that FDA is examining whether the Modified Human Draize Test, as it is currently conducted on medical gloves, is a valid means of predicting the sensitization potential of latex or synthetic materials. If FDA finds that the test is not a scientifically sound means to predict latex or synthetic materials hypersensitivity reactions in users, then hypoallergenic claims included in labeling for medical gloves may be considered misleading, and we will move to have the claim removed from labeling for all medical gloves.

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) 594-4692. 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 at (301) 443-6597.

Sincerely yours,

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