



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1999

Mr. S. Segaran
Managing Director
Seltom Pacific Sdn. Bhd.
Lot 25, Jalan PJS 7/17
Sunway Industrial Park
46150 Petaling Jaya,
Selangor, MALAYSIA

Re: K991777
Trade Name: Latex Examination Gloves Powder-Free with
Protein Labeling Claim (50 Micrograms or Less Total
Extractable Protein)
Regulatory Class: I
Product Code: LYY
Dated: July 8, 1999
Received: July 12, 1999

Dear Mr. Segaran

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.

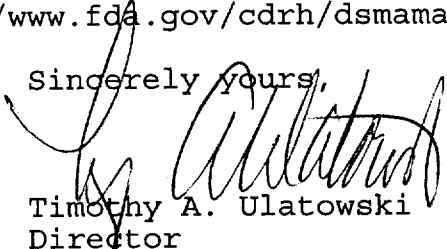
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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 (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

**SELTOM
PACIFIC**

SELTOM PACIFIC SDN. BHD.

(CO. NO. 256686-M)

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INDICATIONS FOR USE

Applicant

SELTOM PACIFIC SDN BHD

510(k) Number

K991777

Device Name

*LATEX Powder Free Patient Examination Gloves WITH A PROTEIN
LABELING CLAIM < 50 MICROGRAMS OF TOTAL EXTRACTABLE*

Indications for Use:-

PROTEIN

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and patient.

It is a single use disposable glove.

Shanti Pr Singh

(Division/Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K991777