DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Mr. Ken Huang
Sales Manager
Sheen More Enterprise Company, Limited
No. 16, Tou Kung Six Road, Tou-Liu
Expanded Industrial Park, Tou-Lin
Yun-Lin, TAIWAN

Re: K001637
Trade Name: Disposable Powder-Free Nitrile Exam Glove, Green Color
Regulatory Class: I
Product Code: LZA
Dated: May 10, 2000
Received: May 30, 2000

Dear Mr. Huang:

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,

Susan Runner

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

Enclosure

3.0 **Indications for Use Statement:** Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: SHEEN MORE ENTERPRISE CO., LTD.

510(k) Number (if known): * K001637

Device Name: DISPOSABLE POWDER FREE NITRILE EXAM GLOVES, GREEN COLOR

Indications For Use:

A PATIENT EXAMINATION GLOVE IS A DISPOSABLE DEVICE INTENDED FOR MEDICAL PURPOSE THAT IS WORN ON THE EXAMINER'S HAND OR FINGER TO PREVENT CONTAMINATION BETWEEN PATIENT AND EXAMINER.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____

Per 21 CFR 801.109

(Optional Format 1-2-96)

* For a new submission, do NOT fill in the 510(k) number blank.

Susan Ruose

(Division Sign-Off)

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number _____