DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 - 2000

Mr. Y. F. Hew
Factory Manager
Flexitech Sdn. Bhd.
Lot 5071, Batu 5 ½ Jalan Meru
41050 Klang
Selangor, Malaysia

Re: K994416
Trade Name: Nitrile Examination Glove, Polymer Coated Powder Free, Blue
Regulatory Class: I
Product Code: LZA
Dated: December 20, 1999
Received: December 23, 1999

Dear Mr. Hew:

This letter corrects our substantially equivalent letter of February 3, 2000, regarding the Device Name and Product Code.

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

FLEXI

FLEXITECH SDN. BHD.

Company No: 165532 - M

Lot 5071, Batu 5 ½, Jalan Meru, 41050 Klang, Selangor, Malaysia.

Tel: 603-3920188 Fax: 603-3920228

3.0 **Indications for Use Statement.**

INDICATIONS FOR USE

Applicant : FLEXITECH SDN BHD

510(k) Number K994416

Device Name: Polymer Coated Powder Free Nitrile Examination Gloves, BLUE

Indication For Use :

This glove is disposable and intended for medical purpose that is worn on the examiner's hand 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number ~~K994354~~ K994416

cription Use
Per 21 CFR 801.109

OR Over-The-Counter : X
(Optional Format 1-2-96)