FORMOSA GLOVE INDUSTRIAL CO., LTD.

NO. 10-8, MA-KUO-LI, MATOU TOWN, TAINAN HSIEN, TAIWAN, R.O.C.
TEL: 002-886-6-570-1885~6 FAX: 002-886-6-570-0388

SEP 10 1999

K992588

510 (k) Summary

Date Prepared : July 30, 1999

1. Applicant

Formosa Glove Industrial Co., Ltd.
No 10-8, Ma-Kuo-Li,
Matou Town, Tainan Hsien
Taiwan
Tel: 886-6-570-1885 Fax: 886-6-570-0388

2. Contact Person

Dr. Tiang S. Chang
1016 Seward Avenue
Westfield, N. J. 07090
Tel: 908 233-3571 Fax: 908 233-0925 E-mail: tschang@earthlink.net

3. Name of Device:

Classification Name	Patient Examination Glove
Common Name:	Blue Nitrile Examination Glove, Powder-free
	Synthetic Powder-free Examination Glove, Nitrile

4. Description:

Classified by FDA's General and Plastic Device Panel as Class I (21 CFR 880.6250), nitrile patient examination gloves, powder-free, 80 LZA. Meets all requirements of ASTM D5250, Standard for poly(vinyl chloride) gloves for medical application. Also meets all requirement of ASTM D3578, Standard for rubber examination gloves except for ultimate elongation before aging.

5. Intended Use

A disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

FORMOSA GLOVE INDUSTRIAL CO., LTD.

NO. 10-8, MA-KUO-LI, MATOU TOWN, TAINAN HSIEN, TAIWAN, R.O.C.
TEL: 002-886-6-570-1885~6 FAX: 002-886-6-570-0388

6. Comparison to Predicate Device and Equivalence

Non-clinical Performance Date:

Applicant device conforms fully to ASTM D5250, Standard for poly(vinyl chloride) gloves for medical application. It also meets all requirements of ASTM D3578, Standard for rubber examination gloves, except for ultimate elongation before aging. This device is substantially equivalent to those currently in commercial distribution.

Clinical Performance Date:

The results of repeated insult patch test (modified Draize test, human study) suggest the applicant device did not induce clinically significant irritation nor have any evidence of induced allergic contact dermatitis in the human subjects.

7. Conclusions:

This device is safe, effective and substantially equivalent to those currently in commercial distribution. It conforms fully to ASTM D5250, Standard for poly(vinyl chloride) gloves for medical application and applicable 21 CFR requirements for label and marking. It also meets all requirements of ASTM D3578, Standard for rubber examination gloves, except for ultimate elongation before aging. The results of a repeated insult patch test suggest that the device does not induce clinically significant irritation nor show any evidence of induced allergic contact dermatitis in human subjects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1999

Formosa Glove Industrial Co., Ltd.
C/O: Dr. Tiang S. Chang
Official Correspondent
1016 Seward Avenue
Westfield, New Jersey 07090

Re: K992588
Trade Name: Blue Nitrile Patient Examination Glove, Powder-free
Regulatory Class: I
Product Code: LZA
Dated: July 30, 1999
Received: August 2, 1999

Dear Dr. Chang:

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) 594-4690. 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

FORMOSA GLOVE INDUSTRIAL CO., LTD.

NO. 10-8, MA-KUO-LI, MATOU TOWN, TAINAN HSIEN, TAIWAN, R.O.C.
TEL: 002-886-6-570-1885~6 FAX: 002-886-6-570-0388

Indications for Use

Applicant: Formosa Glove Industrial Co., Ltd.

510(k) Number (if known): K992588

Device Name: Blue Nitrile Patient Examination Glove, Powder-free

Indications for Use:

A patient examination glove is a disposable device intended for medical purposes 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)

Clinton S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992588

Prescription Use_____ OR Over the Counter Use X
Per 21 CFR 801.109

(Optional Format 1-2-96)