



K980802

MAR 25 1998

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Green Valley, AZ 85614
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510(k) SUMMARY

Submitted By: Janna Tucker & Associates
19001 S. Richfield #185
Green Valley, AZ 85614
Phone: 520-625-2904
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Contact Person: Janna P. Tucker, Official Correspondent for
Sinochem Ningbo Latex Gloves Factory

Date of Submission: 27 February 1998

Device Name: Nitrile Exam Gloves, Powder-Free, Blue

Proprietary Name: (Multiple Labels) Nitrile Exam Glove, Powder Free, Blue

Labels/Labeling: This device will be marketed to healthcare professionals at dentist,
and doctor offices, laboratories, clinics and hospitals through its
intended use.

Intended 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.

Substantial Equivalence:

This device is equivalent to those in commercial distribution. They are to be worn as a protective device on the examiner's hand or finger.

Both in its intended use and/or physical characteristics, this device is equivalent to devices currently marketed by U.S. companies. It is **substantially equivalent** to the device manufactured by Sinochem Ningbo Latex Gloves Factory for a Nitrile Exam Glove, Powder-Free, White K974710.

K980802

Test Results (Means
and/or Results):

This device has met or exceeded the following
standards/tests:

ASTM D 3578-95

ASTM D 5151 FDA Water Leak Test (before & after aging)

Nitrile Glove Draft ASTM, Sept 97.

Bio-Compatibility

 Dermal Sensitization

 Primary Skin Irritation

Bio-Burden (bacteria/mold)

Conclusions:

This device is substantially equivalent to the Sinochem Ningbo
Latex Gloves Factory device approved under K974710.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1998

Sinochem Ningbo Latex Glove Factory
•C/O Ms. Janna P. Tucker
Official Correspondent for Sinochem Ningbo Latex Glove Factory
Janna Tucker & Associates
19001 South Richfield #185
Green Valley, Arizona 85614

Re: K980802
Trade Name: Nitrile Exam Glove, Powder-Free, Blue
Regulatory Class: I
Product Code: LZA
Dated: February 27, 1998
Received: March 2, 1998

Dear Ms. Tucker:

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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

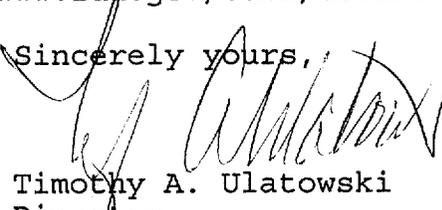
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

INDICATIONS FOR USE

APPLICANT: Sinochem Ningbo Latex Gloves Factory
510(K) NUMBER: K980802
DEVICE NAME: Nitrile Exam Glove, Powder-Free, Blue

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)

Chun S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980802

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)