K991821

JUL - 1 1999

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NINGBO YUJIANG PLASTIC & RUBBER CO., LTD
NITRILE EXAMINATION GLOVE, POWDERED

Submitter: Janna Tucker & Associates
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Contact Person: Janna P. Tucker, President, Janna Tucker & Associates

Date Prepared: May 26, 1999

Trade Name: (Multiple) Nitrile Examination Glove, Powdered
Common Name: Nitrile Exam Glove, Powdered
Classification Name: Nitrile Examination Glove, Class I, 80LZA

Summary of Safety and Effectiveness: Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "... (510(k) Summaries and 510(k) Statements ..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the preparer.

NEW DEVICE NAME: NITRILE EXAMINATION GLOVE, POWDERED

PREDICATE DEVICE NAME: Nitrile Exam Glove, Powder-Free K980677, everything is the same process except for adding powder to finished glove.

Device Description: The device is powdered Nitrile Exam Gloves. They are non-sterile, single use, disposable gloves.

Intended Use: This powdered Nitrile exam glove is intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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Indications Statement:	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.
Technological Characteristics	This Nitrile exam glove has the same technological characteristics as predicate devices. The device is manufactured in standard sizes.
Performance Data:	The device has met and/or exceeded the requirements of the following standards and laboratory tests: ASTM D3578-95 Primary Skin Irritation Study Dermal Sensitization Study FDA Water Leak, before & after aging at AQL 1.5 All tests were performed in a certified testing laboratory.
Conclusions:	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the device is substantially equivalent to other like devices under the Federal Food, Drug, and Cosmetic Act. The predicate device is the powder-free Nitrile Exam Glove, same manufacturer, (K980677), except this new glove is powdered.

JANNA P. TUCKER, President
Janna Tucker & Associates
Official Correspondent for
Ningbo Yujiang Plastic & Rubber Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -1 1999

Ningbo Yujiang Plastic & Rubber Company
c/o Ms. Janna P. Tucker
Official Correspondent
Janna Tucker & Associates
198 De La D'emerald
Sparks, Nevada 89434-9550

Re: K991821
Trade Name: Nitrile Examination Glove, Powdered, Blue
Regulatory Class: I
Product Code: LZA
Dated: May 26, 1999
Received: May 27, 1999

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 (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

INDICATIONS FOR USE

APPLICANT: NINGBO YUJIANG PLASTIC & RUBBER CO., LTD

510(K) NUMBER: K991821

DEVICE NAME: **Nitrile Examination Glove, Powdered, 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)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of Dental, Infection Control, General Hospital Devices
510(k) Number K991821