APR 2 1 2011

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K103770

1. **Owner's Identification:**

Mr. Shen Xiaolin
Syntex Healthcare Products Co., Ltd.
No 1 Fanjiazhuang Industrial Zone,
Xinji City, Hebei Province, China 052360
Tel: 86-311-83980319

Submitter: Kathy Liu
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611
Date Summary Prepared: February 19, 2011

2. **Name of the Device:**

Syntex Healthcare Products Co., Ltd.
Powder Free Nitrile Examination Glove, Pink
Common Name: Exam Gloves

3. **Predicate Device Information:**

Hong Xin Rubber Products Co., Ltd
Powder Free Nitrile Examination Gloves, Blue (K070861)

4. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Polymer Patient Examination Gloves, 80 LZA, and meets all requirements of ASTM standard D 6319-00a (2005)e1.

5. **Intended Use of the Device:**

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. **Comparison to Predicate Devices:**

Syntex Healthcare Products Co., Ltd.'s Powder Free Nitrile Examination Glove, Pink is substantially equivalent in safety and effectiveness to the Hong Xin Rubber Products Co., Ltd's Powder Free Nitrile Examination Gloves, Blue.

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Technological Characteristics	Comparison Result
Intended use	Identical
Indications for use	Identical
Target population	Identical
Anatomical sites	Identical
Where used (hospital, home, ambulance, etc)	Identical
Energy used and/or delivered	Identical (Not applicable)
Human factors	Identical
Design	Similar
Performance	Identical
Standards met	Identical
Materials	Similar
Biocompatibility	Identical
Compatibility with the environment and other devices	Identical
Sterility	Identical (Not applicable)
Electrical safety	Identical (Not applicable)
Mechanical safety	Identical
Chemical safety	Identical
Thermal safety	Identical (Not applicable)
Radiation safety	Identical (Not applicable)

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:**

Characteristics	Applicable FDA- Recognized Standards	Performance Results
Dimensions	ASTM D 6319-00a (2005)e1	Meets
Physical Properties	ASTM D 6319-00a (2005)e1	Meets
Freedom from holes	ASTM D 6319-00a (2005)e1	Meets
Residual Powder Test	ASTM D 6319-00a (2005)e1 ASTM D6124-06	Meets
Primary Skin Irritation and Skin Sensitization	ISO 10993 Part 10 16CFR 1500.41 16CFR 1500.3	Meets

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8. **Labeling:**
There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

9. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

10. **Conclusions:**
Syntex Healthcare Products Co., Ltd.'s Powder Free Nitrile Examination Glove, Pink conform fully to ASTM D6319-00a (2005)e1standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited. Drawn from the complete list of non-clinical tests, the device herein mentioned is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Syntex Healthcare Products Company, Limited
C/O Ms. Kathy Liu
Project Manager
Surprotect, Incorporated
3973 Schaefer Avenue
Chino, California 91710

APR 2 1 2011

Re: K103770
Trade/Device Name: Powder-Free Nitrile Examination Glove, Pink
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 3, 2011
Received: March 14, 2011

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

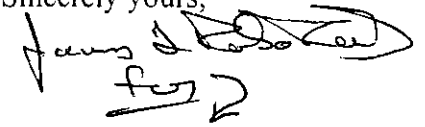
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A

INDICATION FOR USE

510 (k) NUMBER (~~IF KNOW~~): K103770
APPLICANT: Syntex Healthcare Products Co., Ltd.
DEVICE NAME: Powder Free Nitrile Examination Glove, Pink

INDICATIONS FOR USE:

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/ OR Over-The-Counter-Use ___√___
(Part 21 CFR 801 Subpart D) (21CFR 801Subpart C)

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Mansi-Williams
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103770