K042879

JAN 13 2005

APPENDIX L

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR POWDER-FREE BLUE NITRILE EXAMINATION WITH VANILLA SCENTING

Submitted For : SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand.

Submitted By: Tucker & Associates
Official Correspondent for SGMP Co Ltd
Janna P. Tucker, President – CEO
198 Avenue de la D'emerald, Sparks, NV 89434-9550
Phone No : 775-342-2612 Fax No : 775-342-2613
E-mail: Tuckerjan@aol.com

Equivalent Predicate Device: POWDER FREE NITRILE EXAM GLOVES which was granted a 510 (k) # K000868 as shown in APPENDIX M

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:
Trade Name – NON-STERILE POWDER FREE BLUE NITRILE EXAMINATION GLOVES WITH VANILLA SCENTING
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I nitrile patient examination glove 80LZA, powder free and meeting all the requirements of ASTM-D6319-00aE1 Standard Specification for Nitrile Examination Gloves for Medical Application.

Device Description:
Class I nitrile patient examination gloves 80LZA, powder free and meeting all the requirements of ASTM-D6319-00aE1 Standard Specification for Nitrile Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

SGMP Company Limited
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K042879
Trade/Device Name: Non-Sterile, Powder-Free Blue Nitrile Examination Gloves with Vanilla Scenting
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: December 31, 2004
Received: January 4, 2005

Dear Ms. Tucker:

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.

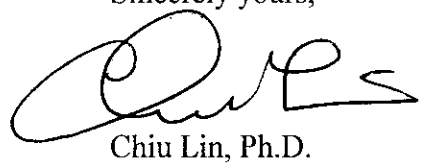
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K042879**

Device Name: **NON-STERILE, POWDER-FREE BLUE NITRILE EXAMINATION GLOVES WITH VANILLA SCENTING**

Indications For Use: **This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.**

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) Number: K042879