Powder Free Nitrile Examination Gloves – 510K Submission

Attachment # 7 – 510(k) Summary

APR 19 2012

SUMMARY OF 510(k) Submission

A. INFORMATION

1. SUBMITTER'S

NAME:	**Dipped Products (Thailand) Ltd**
ADDRESS:	**82/2 Moo 9, Tumbon Rattapum, Amphur Khuen Nieng, Songkla, 90220,Thailand**
TELEPHONE NUMBER:	**+66 74302100**
CONTACT PERSON:	**Mr. L.G.S. Gunawardana**
DATE SUMMARY PREPARED:	**February 2011**

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME:	**Palm-Pro Powder Free Nitrile Examination Gloves Tested for use with Chemotheraphy Drugs.**
COMMON OR USUAL NAME:	**Palm-Pro Powder Free Blue Nitrile Examination Glove**
CLASSIFICATION NAME:	**Palm-Pro Powder Free Blue Nitrile Examination**

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER	Dynarex Corporation, 10, Glenshaw Street, Orangeburg, NY 10962 USA Non-sterile Powder Free Nitrile Examination Gloves (K 081569)

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:
Nitrile latex films form a barrier to body fluids and bloodborne pathogens

b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:
The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:
Nitrile rubber is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and

flexible. The leaching process removes traces of chemical accelerants that may be chemically irritating. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151 requirements.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS
This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between patient and examiner. Nitrile examination gloves with protein free are suitable in situations where healthcare worker or patient allergic sensitivity may be a factor.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE
Refer Attachment 2 A.

B. DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	**Powder Free Blue Nitrile Examination Gloves**
PERFORMANCE STANDARDS	**ASTM D6319-10**
WATER TIGHTNESS	**ASTM D5151-92**

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	
SAFETY	
RABBIT IRRITATION	**Passes**
GUINEA PIG SENSITIZATION	**Passes**

3. CONCLUSION DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY EFFECTIVENESS, AND PERFORMANCE

The data summaries indicate that the product meets or exceeds acceptable scores in nonclinical tests, and satisfies the requirements for a safe and effective powder free medical glove.

Pursuant to 21 C.F.R.807.87 (j), I, L.G.S. Gunawardana, Managing Director, Dipped Products (Thailand) Ltd, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Managing Director of Dipped Products (Thailand) Ltd, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

L.G.S. Gunawardana
MANAGING DIRECTOR

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

APR 19 2012

Mr. L.G.S. Gunawardana
Managing Director
Dipped Products (Thailand) Ltd.
82/2 Moo 9, Tumbon Rattapum
Amphur Khun Nieng
Songkhla
THAILAND 90220

Re: K111464
Trade/Device Name: Palm-Pro Powder Free Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 12, 2012
Received: April 16, 2012

Dear Mr. Gunawardana:

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,

for 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

K111464

INDICATION S FOR USE

Applicant: Dipped Products (Thailand) Ltd

510 (k) Number (if known): New Application

Device Name: "Palm-Pro Powder Free Nitrile Examination Gloves" OR any other OEM Brand

Indications For Use:

The Palm-Pro Powder Free Nitrile Examination Glove is "a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner."
(21CFR 880.6250)

(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 X

Per 21 CFR 801.109
(Optional Format 1-2-96)

For a new submission, do **NOT** fill in the 510(k) number blank

Elizabeth F. Claxton Will

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

510(k) Number: K111464