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510(k) Summary 510(k) # K050152

Manufacturer's Name: Dipped Products (Thailand) Limited
Facility Address: 400 Deans Road
Colombo 10
Sri Lanka
Telephone number: +66 74 325329
Facsimile Number: +66 74 325730
Contact name: Ian Gordon, VP
Emergo Group, Inc.
Clearwater, FL 33761 USA
727-797-4727 phone
727-797-4757 FAX
Date of Preparation: January 14, 2005

Proposed Device: Palm-Pro and Palm-Pro Premium
Powder-Free Latex Examination Gloves With Protein Content Labeling Claim (50 Micrograms or Less)
Predicate Device: Kimberly Clark Safeskin product, K012815
Ansell Protective Products Accutech Ambi 91-109 product K913766

Description of Device:
A non-sterile, disposable, patient examination glove made of natural rubber latex, powder-free, with or without polymer coating.

The proposed and the predicate devices are Class I patient examination gloves, 80LYY, powder-free, that meets all the requirements of ASTM standard D-3578 and FDA 21 CFR 800.20.

Intended Use: A powder-free patient examination glove is a disposable device made of natural rubber latex material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

Summary of Technological Characteristics:

Characteristics	Standards	Device Performance	SE to Predicate
Dimensions	ASTM D 3578-01a	Meets	Same
Physical Properties	ASTM D 3578-01a	Meets	Same
Freedom from pinholes	ASTM D-3578-01a FDA 21 CFR 800.20	Meets	Same
Powder-Free	ASTM D 6124-01	< 2mg/glove	Same
Protein level	ASTM D-5172-95	< 50µg/g	Same
Biocompatibility	Primary Skin Irritation Dermal Sensitization	Not a skin irritation Not a contact sensitizer	Same

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Substantial Equivalence – Non-clinical Performance Data.

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

No Clinical Performance Data required.

Conclusion

Based on the non-clinical performance data that demonstrates the proposed device is as safe and as effective, and performs as well as or better than the legally marketed device identified herein, it can be concluded that the proposed Powder-Free Latex Examination Gloves are substantially equivalent to currently marketed devices.

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dipped Products (Thailand) Limited
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K050152
Trade/Device Name: Powder Free Latex Patient Examination Gloves with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: January 20, 2005
Received: January 24, 2005

Dear Mr. Lehtonen:

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.

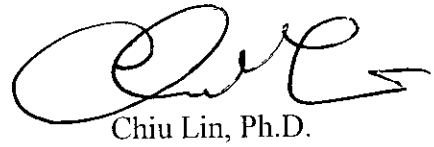
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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

Applicant Name: Dipped Products Limited

510(k) Number (if known): K050152

Device Name:

Common or usual name: powder free latex patient examination gloves with protein content labeling claim (50 micrograms or less)

Trade or Proprietary Name: Palm Pro Premium ,
Model/Catalog Number: 6PF1 (6PF1A24E)

Trade or Proprietary Name : Palm Pro
Model/Catalog Number: 6PF2 (6PF2A24E)

Indications for Use: A powder-free patient examination glove is a disposable device made of natural rubber latex material that may bear a trace amount of glove powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Judith M. Chan D.M.D.

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

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