

K081539

REVISED 510(k) SUMMARY  
OF  
SAFETY AND EFFECTIVENESS

SEP 26 2008

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:

**1. Submitter's Identification:**

Michelle Shih  
Rich Mountain Medical Products Inc.  
No. 8, Jiang Yin Road, Yitang Town  
Pizhou County, Jiangsu Province  
China

**Date Summary : April 15, 2008**

**2. Name of the Device:**

Rich Mountain Medical Products Inc.  
Disposable Powder Free Vinyl Synthetic Exam Gloves With Aloe Vera,  
Green Color

**3. Predicate Device Information:**

Canopus Medical Supply Company Limited.  
Disposable Powder Free Vinyl Synthetic Examination Gloves With  
Aloe Vera, Green Color (K023728)

**4. Device description:**

Classified by FDA's General and Plastic Surgery Device panel as  
Class 1, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Glove, 80LYZ,  
and meets all requirements of ASTM Standard D5250-06.

**5. Intended Use:**

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.

**6. Comparison to Predicate Devices:**

Rich Mountain Medical Products Inc.'s Disposable Powder Free Vinyl Synthetic Exam Gloves With Aloe Vera, Green Color is substantially equivalent to the device manufactured by Canopus Medical Supply Company Limited. (K023728).

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

The standards used for Rich Mountain Medical Products Inc.'s glove production are Based on ASTM D5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection level S-2, AQL 4.0.

The FDA 1000 ml Watertight Test based on ASTM D-5151-06 was also conducted with samplings of AQL 2.5, Inspection level I, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

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

A residual Powder test that based on ASTM D6124-06 for Starch at finished inspection is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per gloves)

**8. Discussion of Clinic Tests Performed:**

Not applicable – There is no Hypoallergenic Claim.

**9. Conclusions:**

Rich Mountain Medical Products Inc's Disposable Powder Free Vinyl Synthetic Exam Gloves With Aloe Vera, Green Color conform fully to ASTM D-5250-06 standard as well as applicable 21CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7.



SEP 26 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Michelle Shih  
Coordinator  
Rich Mountain Medical Products, Incorporated  
No. 8, Jiang Yin Road, Yi Tang Town  
Pizhou County, Jiangsu  
CHINA

Re: K081539

Trade/Device Name: Disposable Powder Free Vinyl Synthetic Exam Glove, With Aloe Vera, Green Color

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: Class I

Product Code: LYZ

Dated: September 15, 2008

Received: September 18, 2008

Dear Ms. Shih:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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: RICH MOUNTAIN MEDICAL PRODUCTS INC.

510(k) Number (if known): APPLIED

Device Name: Disposable Powder Free Vinyl Synthetic Exam.Gloves, With  
Aloe Vera, Green Color

Indications for Use:

A PATIENT EXAMINATION GLOVES IS A DISPOSABLE DEVICE  
INTENDED FOR MEDICAL PURPOSE THAT IS WORN ON THE  
EXAMINER'S HAND OR FINGERS TO PREVENT CONTAMINATION  
BETWEEN PATIENT AND EXAMINER.

Shirley [Signature]  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K081539

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use X  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)