JUL - 2 2002

K021961

510(k) SUMMARY

Submitted For:	**COPIOUMED INTERNATIONAL, INC.** **6f-1, No. 169-12, Sec. 2** **Chang AN East Road** **Taipei, Taiwan, ROC**
Submitted By:	**TUCKER & ASSOCIATES** Official Correspondent for Copioumed International, Inc. **JANNA P. TUCKER,** President-CEO 198 Avenue de la D'emerald Sparks, NV 89434-9550 Phone: 775-342-2612 Fax: 775-342-2613 E-Mail: Tuckerjan@aol.com
Date of Submission:	10 June 2002
Device Name:	**POWDER-FREE POLY-VINYL EXAM GLOVES, COLOR: WHITE** Class I Device, 80LZA
Proprietary Name:	(Multiple Labels) Powder-Free Poly-Vinyl Exam Gloves, Color: White
Labels/Labeling:	This device will be marketed to healthcare professionals at Dentist and Doctor Offices, Laboratories, Clinics and Hospitals through its distributors for the intended use.
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.
Substantial Equivalence:	Both in its intended use and/or physical characteristics, this device is equivalent to devices currently marketed by U.S. companies. Except for color, it is **substantially Equivalent** to the devices manufactured by Shanghai Poseidon Plastic Products Company Limited, (K992979) and Glormed International (K002340)

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Test Results (Means and/or Successful Results:	This device has met or exceeded the following standards and/or tests: ASTM D 5250-00 ASTM D 5151-00 ASTM D 6124-00 Bio-Burden Bio-Compatibility: Dermal Sensitization Primary Skin Irritation
Conclusion:	Except for color, this device is substantially equivalent to the devices approved as K992979 and K002340

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Copioumed International, Incorporated
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K021961
Trade/Device Name: Powder-Free Poly-Vinyl Examination Gloves, White
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: June 10, 2002
Received: June 14, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT: **COPIOUMED INTERNATIONAL, INC.**

510(k) NUMBER: K021961

DEVICE NAME: **POWDER-FREE POLY-VINYL EXAMINATION GLOVES, COLOR: WHITE**

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.

(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 Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021961

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