MAY 2 3 2000

長榮醫療用品有限公司
EVERGREEN MEDICAL PRODUCTS CO., LTD.
No. 1, Evergreen Rd., The North of Beishimen Village, Xiaozuo Town,
Jingxing County, Shijiazhuang City, Hebei 050306, China
Tel: + (86 311) 236 1018, 236 1035 Fax: + (86 311) 236 0670

K994098

510 (K) SUMMARY

Date: May 03, 2000
Total pages: 4

1.0 APPLICANT:

Evergreen Medical Products (Jingxing) Co., Ltd.
No. 1, Evergreen Rd., The North of Beishimen Village,
Xiaozuo Town, Jingxing County,
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China
Tel: +(86 311) 236 1035, 236 0652
Fax: +(86 311) 236 0670
E-mail: chenjul@ms13.hinet.net

2.0 **Contact Person**:

Doreen Feng
Tel: +(86 311) 236 1035, 236 0652
Fax: +(86 311) 236 0670

3.0 DEVICE CLASS: II

PRODUCT CODE: Vinyl (Powder Free) – 80 LYZ

4.0 **SPECIFICATION**: Glove, Patient Examination, Vinyl (Powder Free)
Meet all the current specifications listed under ASTM Specification D 5250-99

5.0 **DEVICE DESCRIPTION**:
Glove, Disposable, Non-sterile, Patient Examination, Vinyl (Powder Free)

6.0 **INDICATION FOR USE (INTENDED USE)**:
A medical gloves is worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient's body, fluids, waste, or environment.

7.0 **INNER SURFACE**: Powder Free

8.0 **BIOCOMPATIBILITY TESTING**:
- Primary Dermal Irritation in Rabbits
- Guinea Pig Sensitization (Buehler)

Issued by Consumer Products Testing Co.

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9.0 **QUALITY CHARACTERISTICS**

SPECIFICATION OF VINYL GLOVES (Ambidextrous)

Size / Spec.	Small	Medium	Large	Ex-Large	Test code
Circumference of Palm (mm) (Inch)	178 6-3/4	210 7-3/4	218 8-1/2	230 9	JIS-S-2045.509
Total Length (+/- 5 mm)	240	245	245	245	JIS-S-2045.5.9
Length of Fingers (mm) Thumbs Index Finger Middle Finger Ring Finger Little Finger	 55 66 74 69 54	 57 70 81 74 50	 61 75 83 79 60	 63 78 92 82 62	JIS-S-2045.5.9
Circumference Fingers (mm) Thumb Index Finger Middle Finger Ring Finger Little Finger	 63 56 59 56 50	 71 64 66 63 57	 78 70 72 69 62	 83 74 76 73 66	JIS-S-2045.5.9
Tensile Strength (Mpa)	Min. 10.0	Min. 10.0	Min. 10.0	Min. 10.0	JIS-S-2045.5.2
Elongation (Min.)	350%	350%	350%	350%	JIS-S-2045.5.2
Weight (g/pc)	7.0	8.0	9.0	9.5	+/- 0.2g
Thickness	Finger Tip Cuff Palm	0.08 mm +/- 0.02 mm 0.09 mm +/- 0.02 mm 0.15 mm +/- 0.02 mm			
Quality Assurance	Under 2.5% Pinhole Rate				FDA Glove 1000ml Water Leak Test

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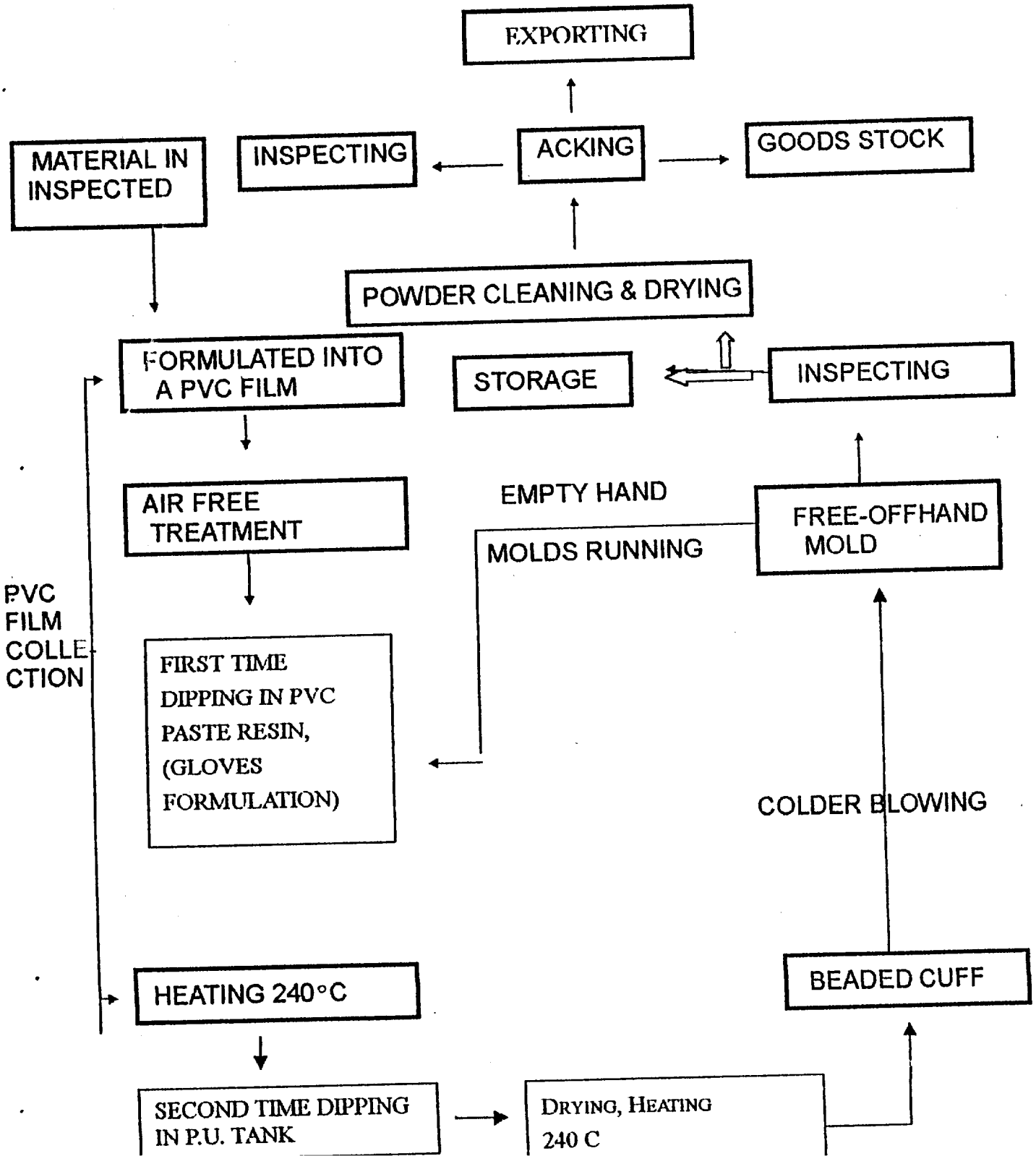
10.0 MANUFACTURING PROCESS OF POWDER FREE VINYL GLOVES:



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Note:
A second time dipping process is adopted to compensate for the lack of donning powder. (Second time dipping process: After the glove is formed on the mold, the second stage of process is exercised by dipping the glove into a Poly Urethane Resin Emersion. Poly Urethane resin emersion is in the category of polymer which contains silicon. The characteristic of Poly Urethane enable to coat a membrane on the gloves which makes the surface of the gloves more lubricant and hence more easy to be worn and to be took off.

Weight of all types of residual powder on medium size glove is 0 milligram per glove.
The gloves are powder free and the process does not include any powder.

11.0 **CONCLUSION:**

The vinyl Patient Examination gloves (powder free) manufactured by Evergreen Medical products (Jingxing) Co., Ltd. meet ASTM D5250-99 performance standard and meet pinhole requirements and labeling claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2000

Ms. Doreen Feng
Evergreen Medial Products (Jingxing) Co. Ltd.
#1, Evergreen Road, The North of Beishimen Village,
Xiazuo Town, Jingxing County,
Shijiazhuang City, Hebei 050306
CHINA

Re: K994098
Trade Name: Vinyl Patient Examination Gloves
Powder-Free
Regulatory Class: I
Product Code: LYZ
Dated: January 21, 2000
Received: May 8, 2000

Dear Ms. Feng:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

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INDICATION FOR USE STATEMENT

Applicant: Evergreen Medical Products (Jingxing) Co., Ltd.
510(K) Number: K994098
Device Name: Vinyl Patient Examination Gloves – Powder Free

Indication for use:
A patient examination glove is a disposable device intended for medical purpose worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Concurrence of CDRH Office of Device Evaluation (ODE)

JB for Chen
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994098

Prescription Use _____ OR Over-The-Counter X
Per 21 CFR 801.109