

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

APR 12 2000

510 (K) SUMMARY

K994099

Date: Feb. 22, 2000

Total pages: 3

1.0 APPLICANT:

Evergreen Medical Products (Jingxing) Co., Ltd.
No. 1, Evergreen Rd., The North of Beishimen Village,
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2.0 Contact Person:

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

3.0 DEVICE CLASS: H

PRODUCT CODE: Vinyl (Pre-Powdered) – 80 LYZ

4.0 SPECIFICATION: Glove, Patient Examination, Vinyl (Pre-powdered)

Meet all the current specifications listed under ASTM Specification D 5250-99

5.0 DEVICE DESCRIPTION:

Glove, Disposable, Non-sterile, Patient Examination, Vinyl (Pre-powdered)

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: Pre-powdered

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

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SPECIFICATION OF VINYL GLOVES (Ambidextrous)

Spec. \ Size	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 CONCLUSION:

The vinyl Patient Examination gloves (Pre-powdered) manufactured by Evergreen Medical products (Jingxing) Co., Ltd. meet ASTM D5250-99 Standard and meet pinhole requirements and labeling claims.

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GENERAL QUALITY CONTROL SCHEME

1.0 PRODUCT

Vinyl Patient Examination Gloves
Pre-Powdered, Non-Sterile

2.0 INTENDED USE

A medical glove is to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient's body, fluid, waste, or environment".

3.0 DONNING POWDER

U. S. P. Absorbable Dusting Powder, Neutral pH
U. S. FDA approved under ANDA (Abbreviated new Drug Application 809535)
U. S. FDA Medical Device Establishment manufacturing Registration Number for manufacturing site.
Name of supplier of USP powder: Shieh-Tai Chemical & Starch Co., Ltd.
Brand name of USP powder: Modified Starch Extra 226.

4.0 COMPONENTS

Polyvinyl Chloride	45.90%
Di-2-Ethylhexyl Phthalate	45.90%
2,2,4-Trimethyl-1, 3-Pentanediol	4.50%
Calcium, Zinc Sterates	2.30%
Epoxidized Soyabean Oil	0.50%
Absorbable Powder for Lubrication	< 120 milligram/glove

5.0 SHAPE

Straight fingers, thumb and fingers in one plane, fist either hand, rolled rim

6.0 SIZE

Small (S), Medium (M), Large (L), Extra-Large (XL)

7.0 COLOR

Natural color, no color additive

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General Quality control scheme: Page 2

8.0 MARKING

Gloves are marked to designated size

9.0 PACKING

As per packing specification

10.0 LABELING

10.1 Control Number

Each packing unit (dispenser box) and outer cartons bears a control number

Example: EVXI991230888

EV Abbreviation of factory name

XI99 Production month and year

123 Internal running order number

0888 Case number

10.2 Manufacturing dating

Each packing unit (dispenser box) or outer cartons bears the manufacturing dating.

10.3 Caution words on the box

“Caution: Users should consider the circumstance of use in deciding whether to remove residual powder from gloves after donning. Powder can be removed by thoroughly wiping gloves with a sterile wet sponge, sterile wet towel, or other effective method.”

11.0 PERFORMANCE REQUIREMENTS FOR QUALITY CHARACTERISTICS

For reference purpose in accordance with ISO 2859 Sampling procedures and Tables for Inspection by Attribute.

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General Quality Control Scheme: Page 3

12.0 QUALITY CHARACTERISTICS

Description	Specification	Assurance Action
<p><u>Dimensions</u></p> <p>Overall Length</p> <p>Width</p> <p>Thickness (Double wall)</p>	<p>240+/- 10 mm</p> <p>Small 83 +/- 5 mm Medium 94 +/- 5 mm Large 105 +/- 5 mm Ex-Large 114 +/- 5 mm</p> <p>Finger 0.48 mm Max. Cuff 0.20 mm Min.</p>	<p>Test method A1 Dimensional control Inspection level S-2 AQL 2.5</p>
<p><u>Chemical Properties</u></p> <p>Inside pH</p> <p><u>Powder level</u></p> <p>Inside Outside</p> <p><u>Physical Properties</u></p> <p>Before Aging Tensile Strength Elongation at break</p> <p>After Aging (70°C, 166 hours) Tensile Strength Elongation at break</p>	<p>7 +/- 1</p> <p>max. 2.5 +/- 1.0 by weight max. 1.0% by weight</p> <p>Min. 10 Mpa Min. 350%</p> <p>Test method A4 Min. 10 Mpa Min. 350%</p>	<p>Test method A2 Inspection level S-2 AQL 2.5</p> <p>Test method A3 Inspection level S-2 AQL 2.5</p> <p>Test method A4 Inspection level S-2 AQL 2.5</p> <p>Inspection level S-2 AQL 2.5</p>

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General Quality Control Scheme: Page 4

13.0 INTERNAL ATTRIBUTIVE RELEASE INSPECTION

Examination

Sampling for examination accordance with ISO 2859 Sampling Procedures and Tables for Inspection by Attributes.

Unit for Examination: one (1) glove

If several defects are found on one glove, only the most serious defect (i. e. lowest category) is evaluated. The acceptance criteria are based on the number of defective observed in a sample.

14.0 PIN HOLE AND VISUAL DEFECTS

Assurance Action

Sampling Inspection by Air inflation and cuff sorting (method A5), inspection level II

Performance requirements:

Category of Defect	AQL
1	1.0
2	2.5

15.0 FINAL GLOVE RELEASE

15.1 Assurance Action

U. S. FDA Test Method for Leakage Defects published in the Federal Registration of Nov. 31, 1989 (21 CFR Part 800.20)

15.2 Sampling Inspection

AQL 1.5 for leaks

AQL 4.0 for leaks and visual defects aggregated.

Inspection level 1, normal inspection, multiple sampling

16.0 PACKAGING, MARKING, GOOD DELIVERY INSPECTION

Assurance Action

Set-up and patrol inspection at packaging

Supervision of vehicle or vessel loading

17.0 GOOD MANUFACTURING PRACTICE

The gloves are manufactured in compliance with the current Good manufacturing Practice (GMP) requirements in the United States of America as appropriate for patient examination gloves.

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18.0 MICROBIOLOGICAL CLEANLINESS CONTROL

The bioburden of the finished gloves are monitored and recorded. Unusual contaminants are identified. It is attempted to determine their sources and eliminating or reducing their impact.

19.0 CAUTION

Non-sterile examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contamination. If conditions warrant, the user may wish to minimize the risk of infection. In this case, we recommend the decontamination of the gloves prior to use by disinfectants or other effective methods.

20.0 STORAGE

According to ISO 2230

Keep storage areas cool, dry and dust free, avoid ventilation.

Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents.

Cooper ions discolor the gloves.

21.0 REFERENCED TEST METHODS

A. 1 Physical Dimensions

Adherence to ASTM D 5250, for length and width press ruler on the flat glove. Measure double film thickness of an intact glove, and report the median of not less than three measurements at different locations.

A. 2 Surface pH of Glove Inside

Warm 50 ml distilled water to 38 +/- 2°C. Fill the glove and twist to close the cuff end. Wash the glove inside and squeezing. Pour content into a beaker and measure pH.

A. 3 Residual powder

5 air dried gloves are weighted together and afterwards rinsed in water to remove powder. Then the gloves are air dried to constant weight for approximately 12 hours. The quantity of powder is determined by the decrease in weight. Limiting values apply to the median of at least 10 results.

A. 4 Physical Requirements

Adherence to ASTM D 3578. Use same glove to compare before and after aging. Report the median of not less than 5 test results for each requirements.

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A. 5 Air Inflation and Cuff Test

Partial adherence to BS 4005, Single Use Sterile Surgical Rubber Gloves, Appendix C. Inflate glove with air approximately to a diameter of 200 mm and fan in front of face. Listen for air leakage and feel it. Visually examine for defects. Stretch cuff next to edge and inspect visually. Validated against FDA water leak test.

22.0 LIST OF DEFECT

Category	Defect	Test method
1	Holes, cuts, tears	Visual, Sensual
2	Pleats and Lumps in critical area	Visual
	Contents not as specified (size, former type)	Visual
	Dirty/foreign spot on surface more than 2 per glove or > 0.5 mm	Visual
	Embedded particles > 1 mm, more than 2 per glove	
	Thin spots	
	Discoloration, blooming	
	Torn, broken or open bead	
	Pleats, lumps in non-critical area	

- End of document -



APR 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Doreen Feng
Evergreen Medical Products (Jingxing) Co., Ltd.
No. 1, Evergreen Road
The North of Beishimen Village
Xiaozuo Town, Jingxing County
Shijiazhuang City, Hebei 050306
CHINA

Re: K994099
Trade Name: Vinyl Patient Examination Gloves- Pre-
powdered
Regulatory Class: I
Product Code: LYZ
Dated: February 22, 2000
Received: April 3, 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.

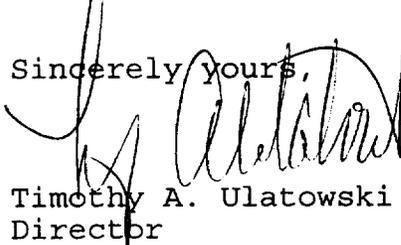
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4690. 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

恆 綠 醫 藥 有 限 公 司

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INDICATION FOR USE STATEMENT

Applicant: Evergreen Medical Products (Jingxing) Co., Ltd.
510(K) Number: K994099
Device Name: Vinyl Patient Examination Gloves – Pre-powdered

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)

Cherie S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(K) Number K994099

Prescription Use _____
Per 21 CFR 801.109

OR Over-The-Counter X