

WEMBLEY RUBBER PRODUCTS (M) SDN BHD (No: 147817-V)

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CONTACT PERSON : MR. Y. W. CHOW

510 (K) SUMMARY

1. **Trade Name** : CHEMO PLUS POWDER FREE BLUE LATEX EXAMINATION GLOVES (PROTEIN CONTENT LABELING)

2. **Common Name** : Examination Gloves

3. **Classification Name** : Patient Examination Glove

4. **Substantial Equivalence** :

Class I latex patient examination glove 80 LZC, powder free, protein content labeling, that meets all of the requirements of ASTM standard D3578-91.

5. **Description of device** :

Class I latex patient examination glove 80 LZC, powder free, protein content labeling, that meets all of the requirements of ASTM standard D3578-91.

6. **Intended use of device** :

The gloves are intended to be worn on the hand of healthcare personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the chemotherapy agents and also can be used to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.

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7. Summary of Performance data :

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Performance data of gloves to ASTM D 3578-91 and FDA 1000 ml watertight test.

TEST	ASTM D 3578-91	CHEMO PLUS Powder Free Blue Latex Examination Gloves (Protein Content Labeling)
1. Watertight (1000 ml)	S-4, AQL 4.0	Pass based on AQL of 1.5
2. Length (mm)		
Size XS	-	-
S	min 230	292
M	min 230	304
L	min 230	308
XL	-	-
3. Palm width (mm)		
Size XS	-	-
S	80 ± 10	83
M	95 ± 10	95
L	111 ± 10	106
XL	-	-
4. Thickness (mm)		
Finger	min 0.08	0.46
Palm	min 0.08	0.27
5. Physical Properties		
<u>Before Ageing :</u>		
Tensile Strength (MPa)	min 21	30.78
Ultimate Elongation (%)	min 700	839
<u>After Ageing :</u>		
Tensile Strength (MPa)	min 16	27.41
Ultimate Elongation (%)	min 500	845
6. Powder Content	-	below 2 mg / glove
7. Moisture Content	-	max 0.8% / glove
8. Protein Content	-	below 50 microgram / gram

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8. **Substantial Equivalence based on assessment of Non-Clinical performance data**

The performance test data of device as shown above indicate that this glove meets requirements of ASTM D 3578-91.

Protein content tested on recently manufactured and accelerated ageing gloves using ASTM D5712 is below 50 microgram / gram.

9. **Conclusion**

This glove exceed the ASTM D 3578-91 requirements, meet pinhole FDA requirements, and below 50 microgram / gram protein content labeling claim.

Date Summary Prepared : June 17, 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1999

Mr. Chow Yue Wah
Vice President QA/RA
Wembley Rubber Products (M) Sdn. Bhd.
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru
Salak Tinggi, 43900 Sepang, Selangor Darul
Ehsan, MALAYSIA

Re: K972615
Trade Name: Chemo Plus Powder-Free Blue Latex
Examination Gloves (Protein Labeling Claim 50
Micrograms or Less)
Regulatory Class: I
Product Code: LYY
Dated: November 10, 1998
Received: November 17, 1998

Dear Mr. Chow Yue Wah:

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 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). 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.

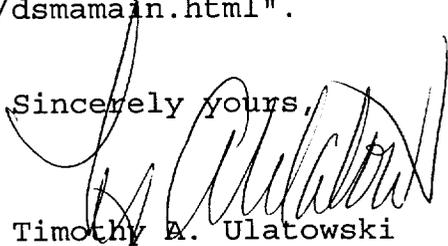
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 pre-market 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" (21CFR 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/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

510(k) Number (if known) : K972615

Device Name : CHEMO PLUS POWDER FREE BLUE LATEX EXAMINATION GLOVES (PROTEIN CONTENT LABELING) 50 MICROGRAMS OR LESS

Indications For Use :

1. The chemotherapy examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between examiner and chemotherapy agents.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use X

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972615