

AUG 23 1999

K992107



# GENERAL GLOVES CORP.

通用手套國際股份有限公司

No. 25, Pei Ma, 16 Lin, Tung Chung Village, Tung Shan Hsiang, Tainan Hsien, Taiwan 733, R. O. C.  
台南縣東山鄉東中村16鄰北馬25號TEL:(06)6803675-7, FAX:(06)680-3681

## 510 (k) SUMMARY

[As required by §807.92(c)]

- 1). Submitter's name and address: HTI Trading Group  
3423 Investment Blvd.  
Suite 12  
Hayward, CA 94545

Telephone and Fax numbers of submitter:

Tel: 510-732-9623

Fax: 510-732-9716

Contact person: David Hu, Ph.D., President

Date summary prepared: June 21, 1999



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- 2). Trade name: "G G" vinyl examination gloves powder-free  
 Common name: Exam gloves  
 Classification name: Patient examination glove  
 (per 21 CFR 880.6250)
- 3). Legally marketed device: Class I vinyl patient examination glove 80LYZ, powdered, that meets all the requirements of ASTM D 5250 - 92.
- 4). Description of the device: Class 1 vinyl patient examination glove 80LYZ, powdered, that meets all the requirements of ASTM D 5250 - 92.
- 5). Intended use of device: 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.
- 6a). Technological characteristics compared to ASTM standard D 5250 - 92:

Dimension and tolerance (S-2, AQL 4.0)

	S	M	L	XL	Tolerance	
width	85	95	105	115	+5	ASTM D 5250 (General)
	87	97	107	117	+3	
length	230	230	230	230	min.	ASTM D 5250 (General)
	230	230	230	230	min.	

Biocompatibility data are conducted on the powdered vinyl gloves.



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6a). Physical requirements

Before and after accelerated aging 70 + 2 C for 72 + 2 hours, according to D573. (Inspection level S-2, AQL 4.0)

Tensil strength (Mpa, min)	Ultimate Elongation (% , min)
9.0	300

6b(1). Assessment of performance data (non-clinical tests):

The performance test data is the same as for 807.92(a)96 mentioned immediately above.

6b(2). Assessment of performance data (clinical tests):

Not required.

6b(3). Our gloves meet or exceed the ASTM or equivalent standard.

Our gloves meet FDA pinhole requirements.

Our gloves meet the labeling claims as shown by the data in (a) (6).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 23 1999

General Gloves Corporation  
C/O Mr. David Hu, Ph.D.  
President  
HTI trading Group  
3423 Investment Boulevard # 12  
Hayward, California 94545

Re: K992107  
Trade Name: Baldur Brand Vinyl Powdered Examination Gloves  
Regulatory Class: I  
Product Code: LYZ  
Dated: June 21, 1999  
Received: July 01, 1999

Dear Mr. Hu:

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.

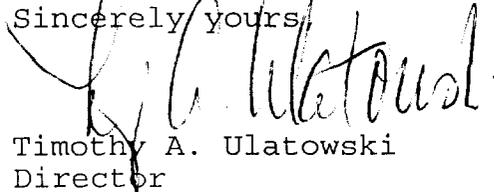
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Hu

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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## STATEMENT OF INDICATIONS FOR USE [807.92(a)(5)].

*Vinyl*  
A patient examination glove is a disposable device intended for medical purposes 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 \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use X  
(Optional Format 1-2-96)

*Chin S. Lin*

(Signature Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K992107