MAY 1 1 2005

K050071

510(k) Summary/Statement Requirement

DEVICE NAME	Powdered and Powder-Free Latex Surgical Gloves
CLASSIFICATION	Class I , 21CFR878.4460
TRADE NAME	MEDISPO and MEDISPO-PF
DEVICE DESCRIPTION	MEDISPO and MEDISPO-PF meet the requirements for surgical gloves described by ASTM D3577.
APPLICANT	H.B.M. USA Co., Inc. HBM Building 98-02 218 Street Queens Village, NY 11429 Contact Person Gordon X. Hu, President (718)776-6666 Ph. (718)776-4666 Fax
PREDICATE DEVICE	This product is already approved and for sale in the European Union and refers to various surgeon's gloves already on the market in the US as predicate devices including: POWDERED LATEX SURGEON'S GLOVES by CEPHAS MEDICAL and MAXTER STERILE POWDER FREE SURGICAL GLOVES.
INDICATIONS FOR USE	MEDISPO powdered surgeon's gloves are sterile disposable devices made of natural rubber latex that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. MEDISO-PF powder-free surgeon's gloves are sterile disposable devices made of natural rubber latex that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.
TESTING	Tests conducted per ASTM D3577, indicate that the product meets the requirements. Tests also indicate no sensitization or irritation.
CONCLUSION	It can be concluded that MEDISPO and MEDISPO-PF surgical gloves will perform according to the performance standards referenced and therefore meet ASTM standards, FDA requirements and labeling claims. This device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 2005

Mr. Gordon X. Hu
President
H.B.M. USA Company, Incorporated
HBM Building, 98-02, 218 Street
Queens Village, New York 11429

Re: K050071
Trade/Device Name: MEDISPO Powdered Surgeon's Gloves and
MEDISPO-PF Powder-free Surgeon's Gloves
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 14, 2005
Received: April 19, 2005

Dear. Mr. Hu:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): K050071

Device Name: MEDISPO powdered surgeon's gloves and MEDISPO-PF powder-free surgeon's gloves

Indications For Use:

MEDISPO powdered surgeon's gloves are sterile disposable devices made of natural rubber latex that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

MEDISPO-PF powder-free surgeon's gloves are sterile disposable devices made of natural rubber latex (that may bear a trace amount of glove powder) and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphy MS

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

510(k) Number: K050071

Page 1 of ____