PT. MAHAKARYA INTI BUANA

Jalan Sei Belumai
Desa Dalu 10 A Dusun I
Tanjung Morawa – 20362
SUMUT – INDONESIA

Tel +62-61-7944880
Fax +62-61-7944882

JUN – 2 2006

510 (K) SUMMARY

K063305

1.0 Submitter:

Name	:	PT. MAHAKARYA INTI BUANA
Address	:	Jl. Sei Belumai, Desa Dalu 10 A Dusun I No. 18 Tanjung Morawa – 20362 SUMUT – INDONESIA
Phone No.	:	+62-61-7944880
Fax No.	:	+62-61-7944882
Date of Summary Prepared	:	

2.0 Contact Person:

Name	:	Mr. V. Nadarajan
Phone	:	+62-61-7944880
Fax No.	:	+62-61-7944882

3.0 Name or the device:

Trade Name	:	1) Senstouch and 2) Multiple or Customers' Trade Name
Device Name	:	Powdered Latex Examination Gloves, Non Sterile
Common Name	:	Examination Gloves
Classification Name	:	Patient Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device:

Class I Examination gloves, LYY, Powdered, that meets all the requirements of ASTM standard D 3578-01 a^{e2} and FDA 1000 ml Water Leak Test.

5.0 Description of The Device

The Powdered Latex Examination Gloves, Non Sterile (Contains 200 micrograms or less of Total Water Extractable Protein per dm^2) meets all the requirements of ASTM standard D 3578-01 a^{e2} and FDA 1000 ml Water Leak Test.

6.0 Intended Use of The Device

The Powdered Latex Examination Glove, Powdered, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's to prevent contamination between patient and examiner.

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7.0 Summary of The Technological Characteristics of The Device

The Powdered Latex Examination Gloves, Powdered, Non Sterile (Contains 200 micrograms or less of Total Water Extractable Protein per dm^2) are summarized with the following technological characteristics compared to ASTM equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimension	D 3578 -01 ae²	Meets
Physical Properties	D 3578 -01 ae²	Meets
Freedom from Pinholes	D 3578 -01 ae² FDA 21 CFR 800.20	Meets
Powder Residue	D 3578 -01 ae² D6124 - 01	< 10 mg/dm^2
Water Soluble Protein Content	D 3578 -01 ae² D 5712 - 99	< 200 $\mu g/dm^2$
Biocompatibility	Primary Skin Irritation in Rabbits	Passes
	Dermal Sensitization	Passes

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above. The samples are from the final product.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

The sample items used during the Primary Skin Irritation Test and the Dermal Sensitization Test is from the final product.

10.0 Conclusion

It can be concluded that The Powdered Latex Examination Gloves, Non Sterile (Contains 200 micrograms or less of Total Water Extractable Protein per dm^2) will perform according to the gloves performance standards referenced in Section (7) above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, 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

JUN 2 2006

Mr. V. Nadarajan
Manager, QA/RA
Jalan Sei Belumai
Desa Dalu 10 A Dusun 1 No. 18
Tanjung Morawa-20362
SUMUT-INDONESIA

Re: K053305
Trade/Device Name: Senstouch Powdered Latex Examination Glove, Non Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: May 10, 2006
Received: May 15, 2006

Dear Mr. Nadarajan:

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.

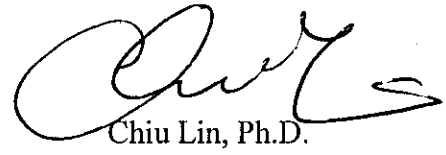
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known): K053305

Device Name: POWDERED LATEX EXAMINATION GLOVE, NON STERILE

Indications For Use:

A Powdered Latex Examination Glove Non Sterile is a disposable device made of natural rubber latex that bears powder to facilitate donning and is intended to be worn on the hand of finger(s) for a medical purpose to provide a barrier againts potentially insfectious material and other contaminations.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(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)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K053305