



PT. MAHAKARYA INTI BUANA

Jl. Desa Dalu X-A, Dalu 10
Deli Serdang – T. Morawa
Sumatera Utara – 20362
Indonesia

Tel +62-61- 30007150, 51, 52, 53
Fax +62-61- 30007156

Date : May 3, 2011

510 (K) SUMMARY

1.0 Submitter:

Name : PT MAHAKARYA INTI BUANA
Address : Jl. Desa Dalu X-A, Dalu 10
Deli Serdang – T. Morawa
Sumatera Utara - 20362
Phone No. : +62-61-30007150, 51
Fax No. : +62-61-30007156
FDA Registration No : 3005813621

2.0 Contact Person:

Name : (Ms) Lina Ng
Phone : +62-61-30007150,51
Fax No. : +62-61-30007156
E-mail : qa@mhk-ia.com

3.0 Name or The Device:

Trade Name : 1) Senstouch and
2) Multiple or Customers' Trade Name
Device Name : Nitrile Examination Gloves, Powder Free, Non Sterile
(Green, Orange, Violet and White)
Common Name : Patient Examination Gloves
Classification Name : Nitrile Examination Gloves

4.0 Identification of The Legally Marketed Device:

Polymer : Nitrile Latex
Device Class : Class I
Substantial Equivalent
Device Description : Patient Examination Gloves, 21 CFR 880.6250
Product Code : Nitrile – 80LZA
Standard : ASTM D 6319-00a (2005)

5.0 Performance Testing Standard

Water Leak Test : G-1, AQL 1.5
Physical Properties : S-2, AQL 4.0
Physical Properties : S-2, AQL 2.5, Single Sampling
Residual Powder : N = 5
Moisture Content : N = 8
Visual Inspection : Critical Defect AQL 0.65
Major Defect AQL 2.5
Minor Defect AQL 4.0



6.0 Intended Use of The Device

Powder Free Green, Orange, Violet and White Nitrile Examination Gloves, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's to prevent contamination between patient and examiner.

7.0 Summary of The Technological Characteristics of The Device (Performance and Conformance Test Data) :

Technological Characteristics of White Nitrile Examination Gloves, Powder Free, Non Sterile are summarized as below :-

REQUIREMENT	REFERENCE STANDARDS	DEVICE PERFORMANCE	STANDARD SPECIFICATION
Physical Dimension	D 6319-00a ^{E3}	Length = 246.77 mm Width = 94.46 mm Thickness: - Finger = 0.150 mm - Palm = 0.095 mm - Cuff = 0.082 mm	Length \geq 230 mm Width = 95 ± 10 Thickness \geq 0.05
Physical Properties	D 6319-00a ^{E3}	<u>Unaged:</u> TS = 15.9 MPa UE = 583.4% <u>Aged:</u> TS = 22.3 MPa UE = 569.2 %	<u>Unaged:</u> TS = 14 MPa UE = 500 % <u>Aged:</u> TS = 14 MPa UE = 400 %
Freedom from Pinholes	D 6319-00a ^{E3} FDA 21 CFR 800.20	0 piece found	Acc / Rej = 3 / 4
Moisture Content	In-house	0.67%	0.8%
Powder Residue	D 6319-00a ^{E3} D6124 - 01	0.84 mg/glove	< 2.0 mg/glove
Biocompatibility Accordance with "Consumer Product Safety Commission, Title 16, Chapter II, Part 1500 and ASTM F720-86	Primary Skin Irritation in Rabbits	Pass (Negative)	Pass
	Dermal Sensitization	Pass (Negative)	Pass

Table 7.0 Performance and Conformance Data of White Nitrile Examination Glove



PT. MAHAKARYA INTI BUANA

Jl. Desa Dalu X-A, Dalu 10
Deli Serdang – T. Morawa
Sumatera Utara – 20362
Indonesia

Tel +62-61- 30007150, 51, 52, 53
Fax +62-61- 30007156

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.

Based on the above data and information, the device is substantially equivalent to its predicate device approved for distribution in the United States.

Part 4 of this submission discusses further on substantial equivalent comparison

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not required for gloves for this submission.

10.0 Conclusion

It can be concluded that the Green, Orange, Violet and White Nitrile Examination Gloves, Non Sterile perform according to the gloves performance standards referenced in Section (5) and (7) above and hence meet ASTM standards and FDA requirements.

Conclusively, we therefore claim that this device is substantially equivalent to its predicate device approved by FDA and is safe and effective for its intended for purposes.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pt. Mahakarya Inti Buana
Ms. Lina Ng
QSP Manager
Dalu 10, Deli Serdang
T. Morawa
Sumatera Utara
Indonesia 20362

AUG 12 2011

Re: K111300

Trade/Device Name: Senstouch Nitrile Examination Gloves, Powder Free, Non Sterile
(Green, Orange, Violet and White)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: May 3, 2011
Received: August 3, 2011

Dear Ms. Ng:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

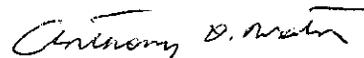
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Device

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K111300

Device Name:

GREEN, ORANGE, VIOLET AND WHITE NITRILE
EXAMINATION GLOVES POWDER FREE, NON-STERILE

Indications For use:

Green, Orange, Violet and White Nitrile examination gloves, Powder Free, Non – Sterile are disposable device and made of Synthetic Polymer that exhibits rubber like characteristics intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Elizabeth F. Jamieson-William
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111300