AUG 2 7 2004

K042101

SEAL POLYMER INDUSTRIES BERHAD
Lot 72706, Jalan Lahat Kawasan Perindustrian Bukit Merah
31500 Lahat, Perak
Tel : 605 – 322 3200, Fax : 605 – 322 2300

1.0 **SMDA 510 (K) SUMMARY**

2.0	Submitter	SEAL POLYMER INDUSTRIES BERHAD Lot 72706, Jalan Lahat Kawasan Perindustrian Bukit Merah 31500 Lahat, Perak, Malaysia
	Tel	(60 5) 322 3200
	Fax	(60 5) 322 2300
	Name of Contact Person	Ms. CHUN CHOOI FONG
	Date of Summary Prepared	August 2, 2004

3.0 Name of Device

Device Name	Powder Free Nitrile Examination Gloves
Common Name	Exam Glove
Classification Name	Nitrile Patient Examination Glove

4.0 Identification of the Legally Marketed Devices

Class 1 Nitrile Patient Examination Glove 80LZA, powder free that meets all the requirements of ASTM Standard D6319-00a^{E3} and FDA requirements.

5.0 Description of The Device

Class 1 Nitrile Patient Examination Glove 80LZA, powder free that meets all the requirements of ASTM Standard D6319-00a^{E3} and FDA Water Leak Test.

6.0 The Intended Use of Glove

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

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7. Summary of Performance Data:

Performance data of gloves based on ASTM D6319-00a^{E3} and FDA 1000 ml watertight test.

TEST	ASTM D6319-00a^{E3}	POWDER FREE NITRILE EXAM GLOVES
1. Watertight (1000 ml)	G 1 AQL=2.5%	Pass GI AQL=2.5%
2. Length (mm) Size XS S M L XL	 Min 230 Min 230 Min 230 Min 230 Min 230	 240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL XXL	 - 80 +/- 10 95 +/- 10 111 +/- 10 - -	 <80 mm 85 +/- 3 mm 95 +/- 3 mm 105 +/- 3 mm 111 +/- 3 mm 120 +/- 3mm
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.05 Min 0.05	 0.08 minimum 0.08 minimum
5. Physical Properties **Before Aging** Tensile Strength (Mpa) Ultimate Elongation (%) **After Aging** Tensile Strength (Mpa) Ultimate Elongation (%)	 Min 14.0 Min 500 Min 14.0 Min 400	 20.7* 609* 22.9* 597*
6. Powder Content	-	Below 2mg / glove

* The average number obtain from Attachment C.

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8. The performance data of the glove as showed above meet the ASTM D6319-00a^{E3} Standard and FDA's requirement.
Powder content is below 2mg per glove, which meet the FDA Requirements.

9. The Biocompatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Biocompatibility Tests.

10. Conclusion

We concluded that the Powder Free Nitrile Examination Gloves meet the below specifications:

- ASTM D6319-00a^{E3} Standard
- FDA pinhole requirements
- FDA minimum powder residual content

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Ms. Chun Chooi Fong
Quality Management System Manager
Seal Polymer Industries Berhad
Lot 72706, Jalan Lahat, Kawasan
Perindustrian Bukit Merah, 31500 Lahat, Perak,
MALAYSIA

Re: K042101
Trade/Device Name: Cashmere Powder Free Nitrile Examination Gloves Green
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 2, 2004
Received: August 4, 2004

Dear Ms. Fong:

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 (301) 594-4618. 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/dsma/dsmamain.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 STATEMENT

Applicant : Seal Polymer Industries Berhad

510(K) Number :

Device Name : Powder Free Nitrile Examination Gloves Green

Indication For Use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay

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

510(k) Number: K042101