

AUG 19 2003

K032077

SEAL POLYMER INDUSTRIES SDN. BHD.
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 SDN BHD
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 July 01, 2003
- 3.0 Name of Device**
- Trade Name Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves (Violet)
- Common Name Exam Glove
- Classification Name Nitrile Patient Examination Glove
- 4.0 Identification of the Legally Marketed Devices**
- Class I 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 I 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}	CASHMERE POWDER FREE NITRILE EXAM GLOVES
1. Watertight (1000 ml)	G I AQL=2.5%	Pass G I 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	- 80 +/- 10 95 +/- 10 111 +/- 10 -	<80 82 – 88 92 – 98 102 – 108 >110
4. Thickness (mm) (Single Layer) Finger Palm	Min 0.08 Min 0.08	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	23.9* 760* 24.3* 640*
6. Powder Content	-	Below 2mg / glove

* indicates the average results from Attachment B2.

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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 Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves meet:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chun Chooi Fong
Quality Assurance Department Manager
Seal Polymer Industries SDN. BHD.
Lot 72706, Jalan, Lahat
Kawasan Perindustrian Bukit Merah
31500 Lahat, Perak, Malaysia

Re: K032077

Trade/Device Name: Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves
(Violet)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 1, 2003
Received: July 7, 2003

Dear Mr. Chooi 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.

Page 2 – Mr. Chooi Fong

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,



Susan Runner, DDS, MA

Interim 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

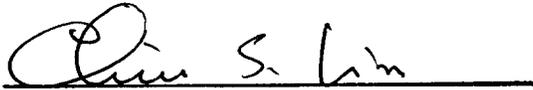
Applicant : Seal Polymer Industries Sdn. Bhd.

510(K) Number: K032077

Device Name : Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves (Violet)

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.



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

510(k) Number: K032077

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: OR Over-The-Counter
Per 21 CFR 80.109