APR 2 2 2002

K020868

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	14th January 2002

3.0 Name of Device

Trade Name	Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves (White)
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 D6319-00 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 D6319-00 and FDA Water Leak Test.

6.0 The Intended Use of Glove

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

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7. Summary of Performance Data:

Performance data of gloves based on ASTM D6319-00 and FDA 1000 ml watertight test.

TEST	ASTM D6319-00	CASHMERE POWDER FREE NITRILE EXAM GLOVES
1. Watertight (1000 ml)	G I 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	 - 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	 0.10 minimum 0.10 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	 15.2 670 19.7 760
6. Powder Content	-	Below 2mg / glove

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8. The performance data of the glove as showed above meet the ASTM D6319-00 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 D6319-00 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

APR 2 2 2002

Mr. Chun Chooi Fong
Quality Assurance Department Manager
Seal Polymer Industries Sdn. Bhd.
LT 72706, Jalan Lahat, Kawasan
Perindustrian Bukit Merah
Lahat, Ipoh, Perak,
MALAYSIA 31500

Re: K020868
Trade/Device Name: Cashmere Non-Sterile, Powder Free Nitrile Examination Gloves (White)
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: March 13, 2002
Received: March 18, 2002

Dear Mr. 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital 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: K020868

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

Indication For Use:

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patients' body, fluids,

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Concurrence of CDRH Office of Device Evaluation (ODC)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020868