NOV 17 1999

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

K993133

Attachment H

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	Mr. CHAN CHIN HONG
	Date of Summary Prepared	September 4, 1999

3.0 Name of Device

	Trade Name	Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Blue) ~~Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Green)~~
	Common Name	Exam Glove
	Classification Name	Patient Examination Glove

4.0 Identification of The Legally Marketed Devices

Class 1 Nitrile Patient Examination Glove 80 LZA, powdered with absorbable dusting powder, that meets all the requirements of ASTM Standard D3578-95 and FDA requirements.

5.0 Description of The Device

Class 1 Nitrile Patient Examination Glove 80 LZA, powdered with absorbable dusting powder, that meets all the requirements of ASTM Standard D3578-95 and FDA Water Leak Test.

6.0 The Intended Use of Glove

A medical gloves 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.

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

Attachment H

7. Summary of Performance Data :

Performance data of gloves based on ASTM D3578-95 and FDA 1000 ml watertight test.

TEST	ASTM D3578-95	CASHMERE POWDERED NITRILE EXAM GLOVES
1. Watertight (1000 ml)	G I AQL=4.0%	Pass GI AQL=4.0%
2. Length (mm)		
Size XS	Min 230	240 mm minimum for all sizes
S	Min 230	
M	Min 230	
L	Min 230	
XL	Min 230	
3. Palm width (mm)		
Size XS	-	75 – 78
S	80 +/- 10	82 – 88
M	95 +/- 10	92 – 98
L	111 +/- 10	102 – 108
XL	-	111 – 115
4. Thickness (mm) (Single Layer)		
Finger	Min 0.08	0.10 minimum
Palm	Min 0.08	0.10 minimum
5. Physical Properties		
Before Aging		
Tensile Strength (Mpa)	Min 14	30.4
Ultimate Elongation (%)	Min 500	640
After Aging		
Tensile Strength (Mpa)	Min 14	30.9
Ultimate Elongation (%)	Min 500	610
6. Powder Content	<=120 mg /glove	<= 120 mg / glove

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

Attachment H

8. The performance data of the glove as shown above meet the ASTM D3578-95 Standard and FDA's requirement.
Powder content is below 120 mg per glove which meet the FDA Requirements.

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

10. Conclusion

We concluded that the Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Blue) and Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Green) meet :

- ASTM D3578-95 Standard
- FDA pinhole requirements
- FDA minimum powder content

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 1999

Mr. Chan Chin Hong
General Manager
Seal Polymer Industries Sdn. Bhd.
Lot 72706, Jalan Lahat,
Kawasan Perindustrian Bukit Merah
31500 Lahat, Perak, Malaysia

Re: K993133
Trade Name: Non-sterile Powdered Nitrile Examination Gloves (Blue)
Regulatory Class: I
Product Code: LZA
Dated: September 17, 1999
Received: September 20, 1999

Dear Mr. Hong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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: K993133

Device Name : Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Blue)
~~Cashmere Non-Sterile, Powdered Nitrile Examination Gloves (Green)~~

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, waste or environment.

.....

Concurrence of CDRH Office of Device Evaluation (ODC)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993133