OCT 29 1998

K981096

SEMPERIT TECHNISCHE PRODUKTE GES.M.B.H.
Bundesstraße 26, A-2632 Wimpassing
Tel.: ++43 2630 310 308, FAX: ++43 2630 310 479

510 (k) Summary

14.03.1998

1.0 APPLICANT

Semperit Technische Produkte Ges.m.b.H.
Modecenterstraße 22
A-1031 Vienna
Phone: ++43 1 79777 490
Fax: ++43 1 79777 630

2.0 CONTACT PERSON

Dipl.-Ing. R. Ehrenfeldner
Semperit Technische Produkte Ges.m.b.H.
Bundesstraße 26
A-2632 Wimpassing
Phone: ++43 2630 310 216
Fax: ++43 2630 310 479

Semperit Industrial Prod. Inc.
Mr. Manfred Reichel
220 Kinderkamack Road
Suite B, Westwood NJ
Phone: (201) 664 5222
(800) 631 2566
Fax: (201) 664 6688

3.0 Device Class: I Type 1
Product Code: 80 FPI/878.4460
(79KGO)

4.0 Specification: Latex patient surgeons´gloves
powederfree - Class I 80 FPI Type 1
meets all of the requirements of ASTM
Standard D 3577-91 and EN 455/1-3

5.0 Device Description: Latex patient surgeons´gloves powderfree

6.0 Intended use: This medical glove is worn on the hand of surgeons, nurses and similar personnel to prevent contamination between health care personnel and the patient.
Supreme is a powderfree glove with an additional inner layer to make donning easily possible (MC = multilayer coating) and TÜV-Productservice claim.
(see attachement 1 and 2)

7.1 Surface treatment: Single side polymer coated, halogenation, siliconization and extensive washing with water in 8 steps. Inside and outside free from glove powder and free of talc. (see att. 9 - 12/6.1 and 6.2)

7.2 Quality characteristics acc. ASTM D3577-91

Description acc. ASTM items								
8.2 Sterility Test	Periodical Validation of the process with Bioservice scientific Laboratories - Germany (attachement 8.2.1/8.2.2)							
8.3 Freedom from holes	Sampling acc. ISO 2859 (att. 9 - 14/13) AQL 1,0							
8.4 Physical Dimension Test	2. Length 270 - 280 mm related to glove size							
	3. Width	6	6,5	7	7,5	8	8,5	9
		79 ±2	84 ± 3	89 ± 3	97 ± 3	104 ± 3	110 ± 3	114 ± 3
	4. Thickness: 017 - 0,26 mm							

8.5 Physical Requirement Test	Before Aging			After Aging	
	Tensile Strength MPa, min	Ultimate Elongation %	Stress at 500 % Elongation	Tensile Strength MPa	Ultimate Elongation %
Spec.	24	750	5,5	18	560

8.6 Powder level	Internal microscopic method 10 powder particels/mm² glove, see att. 9 - 12/6.2.

8 + 9.1 Immunological RAST-inhibition test

8 + 9.2 Skin irritation test on rabbits
8 + 9.3 Maximization test/Sensibilisation of skin on genuine-pig
See attached test resultas (attachement 9 - 14/7, 9 - 14/1 - 6)

} 9 - 14 chapt. 1 - 3 p pages

10. Conclusion
Sempermed powderfree surgeons´gloves Supreme meets ASTM D 3577-91 and EN 455 standard but exceed FDA pinhole requirements (AQL 1,0). It meets the labelling claims as shown by attachements 1(2), 9 - 12/6.1 und 6.2, 9 - 14/13, 9 - 12/6.1/2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

Mr. Richard Ehrenfeldner
Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstrabe 26
A-2632 Wimpassing

Re: K981096
Trade Name: Sempermed Latex Surgeons' Gloves, Powder-Free
Regulatory Class: I
Product Code: KGO
Dated: August 18, 1998
Received: August 21, 1998

Dear Mr. Ehrenfeldner:

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

Semperit Technische Produkte Gesellschaft m.b.H.
A-2632 Wimpassing, Triester Bundesstraße 26
Telefon (02630) 310/216
Telex 16 661 semp a
Telekopierer 02630/310/479

SEMPERIT
Technische Produl

INDICATIONS FOR USE

Applicant: Semperit Technische Produkte Ges.m.b.H.

510(k) Number (if known): K 98 10 96

Device Name: Sempermed Latex Surgeons' Gloves - Supreme, Powder Free

Indications For Use: This medical glove is worn on the hand of surgeons, nurses and similar personnel to prevent contamination between health care personnel and the patient.

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

Concurrenze of CDRH Office of Device Evalution (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K 981096

Prescription Use _____ OR Over-The-Counter X
Per 21 CFR 081.109

* For a new submission, do **NOT** fill in the 510(k) number blank.

(Optional Format 1-2-96)