DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 2, 2017

Semperit Investments Asia Pte. Ltd.
% Thomas Knott
Senior Regulatory Advisor
Benjamin L. England & Associates, LLC
810 Landmark Dr,
Suite 126
Glen Burnie, Maryland 21061

Re: K160781
Trade/Device Name: Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: March 27, 2017
Received: March 29, 2017

Dear Thomas Knott:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160781

Device Name
Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves

Indications for Use *(Describe)*

The Sterile Powder Free Synthetic Rubber Gloves is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SEMPERIT

510(k) Summary

1.0 Submitter :

Semperit Investment Asia Pte. Ltd. (SIA)
8 Jurong Town Hall Road, #29-03 to 06
The JTC Summit
Singapore 609434

Phone No. : +65 6705 2257
Fax No. : +65 6274 6977
Contact Person : Clemens Eichler

Date of Preparation : April 20, 2017

2.0 Name of the Device

Trade Name : Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves

Common Name : Synthetic Rubber Surgical Gloves
Classification Name : Sterile Surgical Gloves

510(K) Number : K160781

3.0 Identification of The Legally Marketed Devices That equivalency is claimed:

Primary Predicate: K013560

Name of the Device: Sempermed® Supreme
Company: SEMPERIT TECHNISCHE PRODUKTE GESELLSCHAFT M.B.H.

4.0 Description of the Device:

Sempermed Syntegra IR is a sterile powder-free surgeon glove. It is a disposable device made of synthetic polyisoprene rubber inside coated with synthetic material to ease donning the glove. This glove is intended to be worn on hands, usually in surgical

settings, to provide a barrier against potentially infectious materials and other contaminants.

5.0 Indications for Use

The Sterile Powder Free Synthetic Rubber Surgical Gloves is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination.

6.0 Summary of the Technological Characteristics of the Device:

The Sterile Powder Free Synthetic Rubber Surgical Gloves is summarized with the following technological characteristics compared to ASTM Specification D3577-09 Standard Specification for Rubber Surgical Gloves or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	**ASTM 3577-09**	Meets standard requirements
Physical Properties	**ASTM 3577-09**	Meets standard requirements
Thickness	**ASTM 3577-09**	Meets standard requirements
Biocompatibility	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass Under the conditions of the studies, the device is non-irritating
	ISO 10993-10:2002/Amd 1:2006(E) Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity – Amendment 1:2006-07-15	Pass Under the conditions of the studies, the device is a non-sensitizer.

Watertight (1000ml)	ASTM D 5151	Pass

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

8.0 Substantial Equivalence Comparison

CHARACTER-ISTICS	STANDARDS	DEVICE PERFORMANCE		CONCLUSION
		Predicate	**Current**	
Applicant		Semperit Technische Produkte GmbH & Co KG	Semperit Investment Asia Pte, Ltd. (SIA)	
510(k) Number		K013560	K160781	
Dimensions	ASTM D3577 ≤ 0.10 mm	Meets, Min 0.10 mm	Meets, Min 0.10 mm	Identical
Physical Properties Before Aging Tensile Strength: Ultimate Elongation: Stress at 500% Elongation:	ASTM D3577 ≥ 17 MPa 650 % min ≤ 7.0 MPa	Meets, 24 MPa min 750% min 7.0 MPa	Meets, 17 MPa min 650% min 7.0 MPa	Identical
Physical Properties After Aging Tensile Strength: Ultimate Elongation	ASTM D3577 ≥ 12 MPa 490 % min	Meets, 18 MPa min 560 % min	Meets, 12 MPa min 490 % min	Identical
Powder Free	ASTM D6124-06	Meets, Requirements of ≤ 2	Meets, Requirements of ≤ 2	Identical

CHARACTER-ISTICS	STANDARDS	DEVICE PERFORMANCE		CONCLUSION
	(≤ 2 mg/glove)	mg/glove for Powder-Free designation per ASTM D3577	mg/glove for Powder-Free designation per ASTM D3577	
Sterile or Non-sterile	-	Sterile	Sterile	Identical
Biocompatibility	Primary Skin Irritation ISO 10993-10	Under the conditions of the studies, the device is non-irritating	Under the conditions of the studies, the device is non-irritating	Identical
	Dermal Sensitization - ISO 10993-10	Under the conditions of the studies, the device is a non-sensitizer	Under the conditions of the studies, the device is a non-sensitizer	Identical
Watertight (1000ml)	ASTM D5151	Passes ASTM D3577 when tested in accordance with ASTM 5151 Inspection Level 1, AQL 1.5	Passes ASTM D3577 when tested in accordance with ASTM 5151 Inspection Level 1, AQL 1.5	Identical
Intended use	-	A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	The Sterile Powder Free Synthetic Rubber Gloves is a single use disposable device intended to be worn by operating room personnel to protect a surgical wound from contamination.	Identical
Material	ASTM D6319-10	Natural Latex	Synthetic Rubber	Similar
Innercoating	-	Synthetic	Synthetic	Identical
Color	-	Natural White	Crème	Similar

CHARACTER-ISTICS	STANDARDS	DEVICE PERFORMANCE		CONCLUSION
Texture	-	Textured (Micro-rough)	Textured (Micro-rough)	Identical
Size	-	5½, 6, 6½, 7, 7½, 8, 8½, and 9	5½, 6, 6½, 7, 7½, 8, 8½, and 9	Identical

9.0 Conclusion

There is no significant difference between the two devices. While the two devices use different materials, both devices meet ASTM standards, FDA's requirement for water leak testing, and other considerations. Since the intended use is the same and they have the same technological characteristics, therefore, the new device is substantially equivalent to the predicate.