April 24, 2022

Avecena Gloves Sdn Bhd
% Mehmet Ormeci
Consultant
MEDCER Uluslararasi Medikal Belgelendirme Anonim Sirketi
Mevlana Bulvari No:221/141 Yildirim Kule
Ankara, Ankara 06830
Turkey

Re: K213775
Trade/Device Name: Glovatex™ White Latex Gloves, Glovanil™ Blue Nitrile Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY, LZA
Dated: March 24, 2022
Received: April 8, 2022

Dear Mehmet Ormeci:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213775

Device Name
Glovatex™ White Latex Gloves, Glovanil™ Blue Nitrile Gloves

Indications for Use *(Describe)*
The Glovatex™ White Latex Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.

The Glovanil™ Blue Nitrile Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.

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.

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510(k) Summary

K213775

510(k) Submitter Name	AVECENA GLOVES SDN BHD
510(k) Submitter Adress	Lot 50592 Sendayan Techvalley Bandar Sri Sendayan Seremban NEGERI SEMBILAN 71950 NEGERI SEMBILAN, Negeri Sembilan, 71950, MALAYSIA
510(k) Submitter Telephone No	+60 - 193 - 477659
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Summary Preparation Date	03/24/2022

Trade Or Proprietary Name	- Glovatex™ White Latex Gloves - Glovanil™ Blue Nitrile Gloves
Common Name	- Latex patient examination glove powder free - Polymer patient examination glove
Classification Name	Non-powder patient examination glove
Class	Class I reserved
Product Code	LYY, LZA

	Subject Device 510k No	Predicate Device 510k No	Predicate Device Manufacturer
Glovatex™ White Latex Gloves	K213775	K192329	JR Engineering & Medical Technologies (M) SDN.BHD.
Glovanil™ Blue Nitrile Gloves	K213775	K200326	Riverstone Resource Sdn Bhd.

Device Description

Glovatex™ White Latex Gloves are manufactured to meet all the current specifications listed under the ASTM Specification D 3578-05 (Reapproved 2015), Standard Specification for Rubber Examination Gloves. They are made from Natural Rubber Latex. These gloves are in white color, non-sterile and powder free.

Glovanil™ Blue Nitrile Gloves are manufactured to meet all the current specifications listed under the ASTM Specification ASTM D6319 - 19 Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from Nitrile compound. These gloves are in Blue color, non-sterile and powder free.

Indications For Use/Intended Use Of The Device

The Glovatex™ White Latex Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.

The Glovanil™ Blue Nitrile Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.

Technological Characteristics

White Latex Gloves

Characteristics	Standards	Device Performance				Comparison
		Predicate		Subject		
510(k) number	-	K192329		K213775		-
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD.		AVECENA GLOVES SDN BHD		-
Name of device	-	Blue Latex Examination Powder Free Gloves		Glovatex™ White Latex Gloves		-
Product Code	-	LYY		LYY		same
Dimensions-Length	ASTM D3578 – 19 Clause 8.4	Length > 220 mm (small) Length > 220 mm (medium, large, X-large)				Similar
		Size	**Average**	**Size**	**Average**	
		Small	304	Small	245	
		Medium	304	Medium	245.6	
		Large	305	Large	247.5	
		X-Large	305	X-Large	244.3	
		XX-Large	305	Not available		
Dimensions-Width	ASTM D3578 – 19 Clause 8.4	Width 70-90mm (small) Width 85-105mm (medium) Width 101-121mm (large) Width 110-130mm (X-large)				Similar
		Small	84	Small	84.4	
		Medium	94	Medium	95.3	
		Large	105	Large	103.7	
		X-Large	114	X-Large	111.5	
		XX-Large	123	Not available		
Dimensions-Thickness - Finger	ASTM D3578 – 19 Clause 8.4	Finger > 0.08 mm		Finger > 0.08 mm		Similar
		Small	0.38	Small	0.14	
		Medium	0.38	Medium	0.14	
		Large	0.38	Large	0.15	
		X-Large	0.38	X-Large	0.15	
		XX-Large	0.38	Not available		
Dimensions-Thickness - Finger	ASTM D3578 – 19 Clause 8.4	Palm > 0.08 mm		Palm > 0.08 mm		Similar
		Small	0.31	Small	0.12	
		Medium	0.31	Medium	0.11	
		Large	0.31	Large	0.11	
		X-Large	0.31	X-Large	0.12	

Characteristics	Standards	Device Performance				Comparison
		Predicate		Subject		
		XX-Large	0.31	Not available		
Physical Properties- Tensile Strength	ASTM D3578 – 19 Clause 8.5.1	Before Ageing Tensile Strength > 18 Mpa		Before Ageing Tensile Strength > 18 Mpa		Similar
		Small	33	Small	24.6	
		Medium	32.9	Medium	23.1	
		Large	32.2	Large	23.7	
		X-Large	31.9	X-Large	22	
		XX-Large	31.1	Not available		
Physical Properties- Tensile Strength	ASTM D3578 – 19 Clause 8.5.2	After Ageing Tensile Strength > 14 Mpa		After Ageing Tensile Strength > 14 Mpa		Similar
		Small	30	Small	23.6	
		Medium	30.6	Medium	21.8	
		Large	29.9	Large	20.9	
		X-Large	29.7	X-Large	22.6	
		XX-Large	28.2	Not available		
Physical Properties- Elongation at Break	ASTM D3578 – 19 Clause 8.5.1	Before Ageing Ultimate Elongation > 650%		Before Ageing Ultimate Elongation > 650%		Similar
		Small	1322	Small	1316	
		Medium	1250	Medium	1346	
		Large	1392	Large	1330	
		X-Large	1130	X-Large	1239	
		XX-Large	1149	Not available		
Physical Properties- Elongation at Break	ASTM D3578 – 19 Clause 8.5.2	After Ageing Ultimate Elongation > 500%		After Ageing Ultimate Elongation > 500%		Similar
		Small	1046	Small	1356	
		Medium	1122	Medium	1385	
		Large	1257	Large	1371	
		X-Large	1011	X-Large	1340	
		XX-Large	1110	Not available		
Powder Free Residue	ASTM D 6124-06/2017	≤2 mg/glove		≤2 mg/glove		Similar
		Small	0.20	Small	0.39	
		Medium	0.21	Medium	0.35	
		Large	0.22	Large	0.37	
		X-Large	0.22	X-Large	0.42	
		XX-Large	0.23	Not available		
Biocompatibility	In vitro Cytotoxicity ISO10993-5 :2009(E)	Non-cytotoxic		Non-cytotoxic		Same
	Primary Skin Irritation-ISO	Not-irritant		Not-irritant		

Characteristics	Standards	Device Performance		Comparison
		Predicate	Subject	
	10993-10:2010(E)			
	Dermal Sensitization-ISO 10993-10:2010(E)	Not-sensitizer	Not-sensitizer	
	Material mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	Non-pyrogenic	Non-pyrogenic	
Freedom From Holes	ASTM D 5151-19	Passes	Passes	Same
Intended use	-	Blue Latex Examination Powder Free Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	The Glovatex™ White Latex Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.	Same
Material	-	Natural Latex	Natural Latex	Same
Color	-	Blue	White	Different
Texture	-	Finger Texture	Finger Texture	Same
Size	ASTM D3578 – 19	Small, Medium, Large, X Large & XX Large	Small, Medium, Large, X Large	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	Same
Powder/Powder free		Powder free	Powder free	Same
Label and Labeling	FDA Label requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same

Although dimensions, physical properties, powder free residue quantity are slightly different between the predicate device and subject device, both of devices comply with the requirements of ASTM D3578 – 19 and ASTM D 6124-06/2017. The predicate device and subject device has different colors. The predicate device has 5 sizes, on the contrary the subject device has only 4 sizes. The subject device does not include XL size. All other specifications are same between the subject device and predicate device.

Blue Nitrile Glove

Characteristics	Standards	Device Performance				Comparison
		Predicate		Subject		
510(k) number	-	K200326		-		-
Manufacturer(s)	-	Riverstone Resource Sdn Bhd.		AVECENA GLOVES SDN BHD		-
Name of device	-	Powder Free Nitrile Examination Glove (Aqua Green)		The Glovanil™ Blue Nitrile Glove		-
Product Code	-	LZA		LZA		same
Dimensions-Length	ASTM D 6319-19 (Clause 7.4.2)	Length > 220 mm (small) Length > 230 mm (medium, large, X-large)				Similar
		Size	**Average**	**Size**	**Average**	
		Small	Meet the requirements of ASTM D 6319-19	Small	239.5	
		Medium		Medium	239.7	
		Large		Large	238.3	
		X-Large		X-Large	239.3	
		XX-Large		Not available		
Dimensions-Width	ASTM D 6319-19 (Clause 7.4.3)	Width 70-90mm (small) Width 85-105mm (medium) Width 100-120mm (large) Width 110-130mm (X-large)				Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	81.7	
		Medium		Medium	88.8	
		Large		Large	104.3	
		X-Large		X-Large	111.3	
		XX-Large		Not available		
Dimensions-Thickness - Finger	ASTM D 6319-19 (Clause 7.4.4)	Finger > 0.05 mm		Finger > 0.05 mm		Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	0.14	
		Medium		Medium	0.14	
		Large		Large	0.14	
		X-Large		X-Large	0.14	
		XX-Large		Not available		
Dimensions-Thickness - Finger	ASTM D 6319-19 (Clause 7.4.4)	Palm > 0.05 mm		Palm > 0.05 mm		Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	0.11	
		Medium		Medium	0.10	
		Large		Large	0.09	
		X-Large		X-Large	0.10	
		XX-Large		Not available		
		Before Ageing		Before Ageing		Similar

Characteristics	Standards	Device Performance				Comparison
		Predicate		Subject		
Physical Properties- Tensile Strength	ASTM D 6319-19 (Clause 7.5.1)	Tensile Strength > 14 Mpa		Tensile Strength > 14 Mpa		
		Small	Meet the requirements of ASTM D 6319-19	Small	707	
		Medium		Medium	819	
		Large		Large	824	
		X-Large		X-Large	840	
		XX-Large		Not available		
Physical Properties- Tensile Strength	ASTM D 6319-19 (Clause 7.5.1)	After Ageing Tensile Strength > 14 Mpa		After Ageing Tensile Strength > 14 Mpa		Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	22.8	
		Medium		Medium	24.3	
		Large		Large	24.0	
		X-Large		X-Large	22.2	
		XX-Large		Not available		
Physical Properties- Elongation at Break	ASTM D 6319-19 (Clause 7.5.1)	Before Ageing Ultimate Elongation > 500%		Before Ageing Ultimate Elongation > 500%		Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	791	
		Medium		Medium	848	
		Large		Large	835	
		X-Large		X-Large	852	
		XX-Large		Not available		
Physical Properties- Elongation at Break	ASTM D 6319-19 (Clause 7.5.1)	After Ageing Ultimate Elongation > 400%		After Ageing Ultimate Elongation > 400%		Similar
		Small	Meet the requirements of ASTM D 6319-19	Small	23.6	
		Medium		Medium	24.5	
		Large		Large	24.2	
		X-Large		X-Large	22.1	
		XX-Large		Not available		
Powder Free Residue	ASTM D 6124-06/2017	≤2 mg/glove		≤2 mg/glove		Similar
		Small	Meet the requirements of ASTM D 6124-06/2017	Small	1.18	
		Medium		Medium	1.91	
		Large		Large	0.81	
		X-Large		X-Large	1.17	
		XX-Large		Not available		
Biocompatibility	In vitro Cytotoxicity ISO10993-5	No information		Non-cytotoxic		Similar
	Primary Skin Irritation-ISO 10993-10	Not-irritant		Not-irritant		
	Dermal Sensitization-ISO	Not-sensitizer		Not-sensitizer		

Characteristics	Standards	Device Performance		Comparison
		Predicate	Subject	
	10993-10			
	Acute Systemic Test ISO 10993-11	Did not induce a systemic toxicity	Did not induce a systemic toxicity	
	Material mediated Pyrogenicity ISO 10993-11/ USP 41<151>	/	Did not produce a pyrogenic response	Different
Freedom From Holes	ASTM D 5151-19	Passes	Passes	Same
Intended use	-	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for overthe-counter use.	The Glovanil™ Blue Nitrile Glove is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.	Same
Material	-	Nitrile compound	Nitrile compound	Same
Color	-	Aqua Green	Blue	Different
Size	ASTM D6319 – 19	Small, Medium, Large, X Large & XX Large	Small, Medium, Large, X Large	Similar
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/non sterile	-	Non sterile	Non sterile	Same
Powder/Powder free		Powder free	Powder free	Same
Label and Labeling	FDA Label requirements	Meets FDA's label and labeling requirements	Meets FDA's label and labeling requirements	Same

Although dimensions, physical properties, powder free residue quantity are slightly different between the predicate device and subject device, both of devices comply with the requirements of ASTM D6319-10 and ASTM D 6124-06/2017. The predicate device and subject device has different colors. The predicate device has 5 sizes, on the contrary the subject device has only 4 sizes. The subject device does not include XL size. More biocompatibility tests were performed to subject device compared to

predicate device. Both devices meet the requirements of ISO 10993-1. All other specifications are same between the subject device and predicate devices.

Summary of Non-Clinical Testing

The Glovatex™ White Latex Gloves meet the requirements of ASTM D3578 – 19, ASTM D 6124-06(2017), ISO10993-5:2009(E), ISO 10993-10:2010(E), ISO 10993-11:2017(E), USP 41<151> and ASTM D 5151-19.

The Glovanil™ Blue Nitrile Gloves meet the requirements of ASTM D 6319-19, ASTM D 6124-06(2017), ISO10993-5:2009(E), ISO 10993-10:2010(E), ISO 10993-11:2017(E), USP 41<151> and ASTM D 5151-19.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the Glovatex™ White Latex Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192329.

The conclusion drawn from the nonclinical tests demonstrates that the Glovanil™ Blue Nitrile Gloves is as safe, as effective, and performs as well as or better than the legally marketed predicate device K200326.