March 15, 2023

M/S Tegamen Safety Products Private Limited
% Avinash Arora
Consultant
Arora 297 Consultancy
229 Deer Ridge Dr
Kitchener, ON N2P2k5
Canada

Re: K223102
Trade/Device Name: Tegamen Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 10, 2023
Received: February 10, 2023

Dear Avinash Arora:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
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
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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.

Submission Number *(if known)*

K223102

Device Name

Tegamen Nitrile Examination Gloves

Indications for Use *(Describe)*

Tegamen Nitrile Patient Examination gloves, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between 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 K223102

As required by 21CFR§807.92

1. 510(k) Submitter

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2. Manufacturer

Tegamen Safety products Ltd
Sp7-52, Ricco Industrial Area Ghiloth Alwar,
Rajasthan, 301705 India

3. Preparation Date: Mar 8, 2023

4. Device Identification

Trade/Proprietary Name:	Tegamen Nitrile Examination Gloves
Common/Usual Name:	Nitrile Examination Gloves
Classification Name:	Patient Examination Gloves
Regulation Number:	21 CFR 880.6250
Product Code:	LZA
Device Class:	Class I
Classification Panel:	General Plastic Surgery/General Hospital

5. Legally Marketed Predicate Device(s)

Device name:	Nitrile Patient Examination gloves, Powderfree, Blue Color
510(k) number:	K143477
Manufacturer:	PRIMUS GLOVES PVT LIMITED PLOT No: 14-A, COCHIN SPECIAL ECONOMIC ZONE, KAKKANAD COCHIN, IN 682037

6. Indications for Use

Tegamen Nitrile Patient Examination Gloves, is a disposable device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between patient and examiner.

7. Device Description

The subject device in this 510(k) Notification is Tegamen Nitrile Examination Gloves, Powder Free. The subject device is a patient examination glove made from nitrile compound, blue color, powder free and non-sterile (Per 21 CFR 880.6250, Class I). The device meets the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

8. Substantial Equivalence Discussion

The following table compares the subject Tegamen Nitrile Examination Gloves to the selected predicate device. The comparisons include the following attributes which forms the basis for determining substantial equivalence:

- Indications for use,
- Technological characteristics, and
- Device performance

Table 1: Comparison of Characteristics

Attribute	Tegamen Nitrile Examination Gloves K223102	Nitrile Patient Examination gloves, Powderfree, Blue (K143477)	Same / Similar / Different
Manufacturer	Tegamen Safety Products Ltd	Primus Gloves Private Ltd	Different
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Device Description	The subject device in this 510(k) Notification is Tegamen Nitrile Examination Gloves, Powder Free. The subject device is a patient examination glove made from nitrile compound, blue color, powder free and non-sterile (Per 21 CFR 880.6250, Class I). The device meets the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	The subject device is a patient examination glove made of synthetic nitrile latex compound. It is non-sterile, powderfree and is Blue in color. The device is ambidextrous and can be worn on either the eft or right hand. The device meets ASTM 06319-10: Standard specification for Nitrile Examination Gloves for Medical Application. The device is for over-the counter single use.	Similar
Materials of Use	Nitrile compound	Nitrile compound	Same
Sterile	No	No	Same
Indications for Use	Tegamen Nitrile Patient Examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.	The examination gloves is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner	Same

Attribute	Tegamen Nitrile Examination Gloves K223102	Nitrile Patient Examination gloves, Powderfree, Blue Color (K143477)	Comparison
Color	Blue	Blue	Same
Size (ASTM D6319-19)	Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Similar
Freedom from Holes (ASTM D6319-19)	Passed AQL2.5	Passed AQL2.5	Similar
Single Use	Yes	Yes	Same
Ambidextrous	Yes	Yes	Same
Physical Properties (ASTM D6319-19)	Before Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 500 After Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 400	Before Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 500 After Aging Tensile Strength Min 14 Mpa Ultimate Elongation Min 400	Similar
Powder Free (ASTM D6319-19)	<2 mg/glove	<2 mg/glove	Similar
Dimensions (ASTM D6319-19)	Overall Length 239 min	Overall Length 240 min	Similar
Thickness (ASTM D6319-19)	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Similar
Biocompatibility - Cytotoxicity	Under the conditions of study cytotoxic	NA	Different Not conducted on predicate device
Biocompatibility – Acute systemic toxicity	Under the conditions of the study no acute systemic toxicity	NA	Different Not conducted on predicate device.

Biocompatibility - SKIN SENSITIZATION - ISO 10993-10: 2010 (E)	Under the conditions of study not a sensitizer	Under the conditions of study not a sensitizer	Similar
Biocompatibility - SKIN IRRITATION - ISO 10993-10: 2010 (E)	Under the conditions of study not an irritant	Under the conditions of study not an irritant	Similar

9 . Non-Clinical Testing Summary

PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the width, length, and thickness of the gloves	Length > 230 mm (240- 400mm) Width 70±10 mm to 120±10 mm (sizes XS to XL) Thickness > 0.05 mm (palm & finger)	**Pass** Length (mm) Mean Value – 239.45 Width (mm) Mean Value – 84.7 (small), 95.9 (medium), 105.8 (large), 115.5 (extra large) Thickness at finger (mm) Mean Value – 13 Thickness at Palm (mm) Mean Value – 0.065
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Requirements Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	**Before Acceleration Aging:** Tensile Strength 14 Mpa min before aging Ultimate Elongation 500 % min before aging **After Acceleration Aging:** Tensile Strength 14 Mpa min after aging Ultimate Elongation 400 % min after aging	**Pass** MPa (MeanValue) – 23.24 before aging MPa (Mean Value) – 22.62 after aging Ultimate Elongation (Mean Value) 851.9 before aging Ultimate Elongation (Mean Value) 808.7 after aging
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	**Pass** Total Defects – 01 (Holes found 1)
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤ 2.0 mg/glove	**Pass** Powder Content (mg/glove) – 1.335

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the potential of the material under test to produce skin irritation in rabbits	Under the condition of study not an irritant	***Under the condition of study not an irritant***
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential of the material both in terms of induction and elicitation in guinea pigs.	Under the conditions of the study not a sensitizer.	***Under the conditions of the study not a sensitizer.***
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method	Under the conditions of study cytotoxic	***Based upon the results obtained in this study and in line with ISO 10993-5:2009, it is concluded that the given test item, Tegamen Nitrile Examination, supplied by Tegamen Safety Products Pvt Ltd., is considered as cytotoxic in undiluted extract, 1:2 ,1:4, 1:8, and 1:16 dilutions. Non-cytotoxic to L-929 cells at 1:32 dilutions***
ISO 10993-11:2017 Biological evaluation of medical devices— Part 11: Tests for acute systemic toxicity	The test item was evaluated for acute systemic toxicity in Swiss Albino Mice	Under the conditions of the study no acute systemic toxicity	***Under the conditions of the study no acute systemic toxicity***

10. Clinical Testing summary

Not applicable - Clinical data is not needed for the subject gloves.

11. Conclusion

The conclusion drawn from the non-clinical test demonstrate that the subject device, Tegamen Nitrile Examination Glove, is as safe, as effective, and performs as well as or better than the legally marketed predicate device.