September 29, 2023

Ineo Tech Sdn Bhd
Pierre Hoerner
Company Director
PT5825, Jalan Cassia Selatan 3/11 Taman Perindustrian
Batu Kawan
Bandar Kassia, Penang 14110
Malaysia

Re: K231973
Trade/Device Name: PolyIsoprene Powder Free Black Colour Radiation Attenuating Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, OPH
Dated: June 25, 2023
Received: July 3, 2023

Dear Pierre Hoerner:

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
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)*
K231973

Device Name
Polyisoprene Powder Free Black Colour Radiation Attenuating Surgical Glove
Model 1: Min. 0.21mm (thickness)
Model 2: Min. 0.29mm (thickness)

Indications for Use *(Describe)*
The polyisoprene powder free, black colour surgical gloves are radiation attenuating and intended to be worn by operating room personal 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.

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K231973: 510(k) SUMMARY

[per 21 CFR 807.92]

1. Submitter Information

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Contact Name:	Dr Pierre Hoerner, Ph.D
Date of summary:	27 Sept, 2023

2. Device Identification

Trade name:	Polyisoprene Powder Free Black Color Radiation Attenuating Surgical Gloves
Classification name:	Surgeon's glove
Product Code:	KGO (primary code); OPH
Regulation number:	21 CFR 878.4460
Device Class:	Class I (general controls)
Assigned 510k number	K231973

3. Identification of Predicate Devices

- 510(k) number K192933 by Emerson & Co. S.r.l is identified as the primary predicate device

- 510(k) number K022873 is considered as reference device to support specific testing or device features.

4. Device Description

The Polyisoprene Powder Free Black Color Radiation Attenuating Surgical Glove is a disposable sterile powder-free medical device made of polyisoprene that is intended to be

worn by operating room personnel to protect a surgical wound from contamination. The glove contains radiation-attenuating particles to reduce the exposure from harmful ionizing scattered or secondary radiation on the operator's hand during fluoroscopic procedures. The glove is proposed in two (2) options. The Model 1 and Model 2 are made with exactly the same material and composition and differ only by their thicknesses and therefore their attenuation properties.

5. Indications for Use

The Polyisoprene Powder Free Black Color Surgical Gloves are radiation attenuating and intended to be worn by operating room personal to protect a surgical wound from contamination.

6. Comparison to Predicate Devices

Characteristic	Subject Device	Primary Predicate Device	Reference Device	Comparison
510(k) number	**K231973**	**K192933**	**K022873**	
Regulation No.	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	Same regulation number
Product Code	KGO (primary) OPH	KGO	KGO	Same product code
Device Class	Class I	Class I	Class I	Same device class
Device type	Powder-free sterile surgical glove	Powder-free sterile surgical glove	Powder-free sterile surgical glove	Same indicated use

Indications for use statement	The polyisoprene powder free, black color surgical gloves are radiation attenuating and intended to be worn by operating room personnel to protect a surgical wound from contamination.	The polyisoprene powder free, black color surgical gloves are radiation attenuating and intended to be worn by operating room personnel to protect a surgical wound from contamination	A powder-free surgeon's glove is a device made of synthetic latex that may bear a trace amount of glove powder and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. The radiation attenuating surgical glove is intended to be used during medical procedures where hands are necessarily exposed to radiation in order to offer some degree of protection to the hand from radiation. This includes surgical procedures that require the use of fluoroscopy or radiography	Similar
Color	Black	Black	Black	Same color
Size Range	6 to 9	6 to 9	6 to 9	Same size range
Use limit of the device	Single use	Single use	Single use	Same use limit
Technology	Latex Dipping & Sulphur vulcanization	Latex Dipping & Sulphur vulcanization	Latex Dipping & Sulphur vulcanization	Same dipping and vulcanization technology.
Elastomer	Non Natural Rubber Latex (PolyIsoprene)	Non Natural Rubber Latex (PolyIsoprene))	Non Natural Rubber Latex (PolyChloroprene)	All gloves are made with Non Natural Rubber Latex elastomer.
RadiationAttenuation Material	(Tungsten based composition)	(Tungsten based composition)	(Tungsten based composition)	All gloves are made without Lead and contain tungsten as Radiation-Attenuation Material composition
Standards met	ASTM D3577 ASTM D5151 ASTM D6124 ASTM D7866	ASTM D3577 ASTM D5151 ASTM D6124 ASTMD7866	ASTM D3577 ASTM D5151 ASTM D6124 ASTM D7866	Same performance standards met

Sterilization	Sterile (SAL 10^6). Radiation.	Sterile (SAL 10^6). Ethylene Oxide	Sterile (SAL 10^{-6}). Radiation	Sterilization process is Radiation or Ethylene Oxide, SAL 10^{-6}
Biocompatibilty See Table below	Meets requirements	Meets requirements	Meets requirements	All met current requirements

7. Summary of Non-Clinical Performance Testing

The Polyisoprene Powder Free Black Color Radiation Attenuating Surgical Glove possesses the following technological characteristics:

Test Method	Test Purpose	Acceptable criteria	Results
ASTM D5151	- Freedom from holes	**Criteria:** AQL 1.5	**PASS** AQL=0.65
ASTM D3577	Physical Dimensions - Length	**Criteria:** Size 6 to 9 ≥265mm Size 6 to 9 ≥285mm	**PASS** All sizes ≥285mm (range:298-301mm)
	- Width	**Criteria:** size 6.0: 76 ± 6mm size 6.5: 83 ± 6mm size 7: 89 ± 6mm size 7.5: 95 ± 6mm size 8: 102 ± 6mm size 8.5: 108 ± 6mm size 9: 114 ± 6mm	**PASS** 83-84mm (size 6.5) 90-91mm (size 7) 96-97mm (size 7.5) 106-107mm (size 8) 110-113mm (size 8.5) 112-115mm (size 9)

Test Method	Test Purpose	Acceptable criteria	Results
	- Thickness	**Criteria:** Min. 0.1mm	**PASS** **Model 1:** Finger: 0.27-029mm Palm: 0.24-0.25mm Cuff: 0.23-0.24mm **Model 2:** Finger: 0.33-0.39mm Palm: 0.33-0.35mm Cuff: 0.31-0.33mm
ASTM D3577	Physical Properties - Tensile Strength	**Criteria:** - Before accelerated aging: 17 MPa min - After accelerated aging: 12 MPa min	**PASS** 18.7-19.6MPa 18.2-18.5MPa
	- Strength at 500%	**Criteria** 7.0 MPa max	**PASS** 4.1-4.9MPa
	- Ultimate Elongation	**Criteria:** - Before aging: 650 % min - After aging: 490 % min	**PASS** 700-720% 620-645%
ASTM D6124	- Residual powder	**Criteria:** <2mg / glove	**PASS** 0.05-0.18mg/glove

Test Method	Test Purpose	Acceptable criteria	Results
ASTM D7866	**Attenuation requirements (***Measured in the thinnest portion of the glove, i.e cuff)*	**Criteria:** 60 kVp: 29% 80 kVp:22% 100 kVp:18% 120 kVp:15%	**PASS** Model 1 60kVp: 42.0-43.0% 80kVp: 34.4-35.0% 100kVp:28.9-29.4% 120kVp: 25.1-25.4% Model 2: 60kVp:50.5-51.3% 80kVp: 42.0-42.7% 100kVp:36.2-36.7 120kVp: 31.2-31.6
Biocompatibility **ISO 10993-10, Skin Irritation**	- Determine if an extract of the product produces skin Irritation	- No skin irritation	**PASS** Under the condition of the study: - No skin irritation was observed. The skin irritation response category of both polar and non-polar extract of the test item in rabbit is negligible.
ISO 10993-10, Dermal Sensitization	- Determine if an extract of the product produces Dermal Sensitization after repeated exposure	- No skin sensitization	- No skin sensitization was produced in guinea pigs.
ISO 10993-11, Acute Systemic Toxicity	- Determine if an extract of the product causes systemic toxicity in vivo	- Meet systemic toxicity test	- The tested glove meets the requirement of acute systemic toxicity test.

Test Method	Test Purpose	Acceptable criteria	Results
ISO 10993-5, Cytotoxicity	- In vitro cytotoxicity on extract	- Comparable cytotoxicity to predicate device	- Both devices exhibited a slight reactivity at 50x dilution concentration.
ASTM D7102-22, Endotoxin	- Determination of bacterial endotoxin on gloves	- Endotoxin level according to ASTMD7102-17 less than 20 EU/device on 3 production batches	- Endotoxin determination performed according to ASTMD7102-17 showed 12.9, 12.8 and 15.4
ISO 21582-21, Pyrogenicity	- Pyrogen testing	- Non pyrogenic	- Extract of test item evaluated for pyrogen test is non pyrogenic and meets the requirements of pyrogenicity test as per US Pharmacopeia

8. Clinical Data

Clinical data is not needed for medical glove 510(k) submissions.

9. Conclusion Statement

The conclusions drawn from the nonclinical tests demonstrate that the Polyisoprene Powder Free Black Color Radiation Attenuating Surgical Glove is as safe, as effective, and performs as well as or better than the legally marketed devices identified.