November 18, 2021

Impertech Industries Ltd.
Vaibhav Rajal
Official Correspondent for Impertech Industries Ltd.
mdi Consultants Inc
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K212046
Trade/Device Name: Impertech Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 14, 2021
Received: October 18, 2021

Dear Vaibhav Rajal:

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,

For 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)*
K212046

Device Name
Impertech Surgical Face Mask

Indications for Use *(Describe)*
The Impertech Surgical Face Mask are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluid. This is a single use, disposable device, provided non-sterile.

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.

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510(k) SUMMARY

The assigned 510(k) number is: K212046.

1. Submitter's Identification:

Impertech Industries Ltd.
20 Derech Barkan St. Barkan Industrial Zone,
Barkan, IL 4482000

Contact Person: Mohamad Khweis
Position: Quality Assurance Manager
Phone: +972-3-9367682
Email: mohamadk@supergum.co.il

Date Prepared: November 15, 2021

2. Name of the Device:

Trade Name: Impertech Surgical Face Mask
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Classification Panel: General Hospital
Regulatory Class: Class II
Product Code: FXX

3. Information for the 510(k) Cleared Device (Predicate Device):

Trade/Device Name: Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask
510(k) Number: K202595
Common Name: Mask, Surgical
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel.
Regulatory Class: Class II
Product Code: FXX

4. Device Description:

The device description for the Impertech Surgical Face Mask is in accordance with the FDA Guidance Document, Surgical Masks –Premarket Notification [510K)] Submissions issued on March 5, 2004. The Impertech Surgical Face Mask is a flat-pleated style mask with elastic ear loops to secure it over the user's mouth and face. The mask consists of three-layers. The inner facing layer is white and is manufactured from spunbond polypropylene (three layers of nonwoven polypropylene). The inner filter material is made of melt blown fiber. The outer facing layer is white and is manufactured from spunbond polypropylene (three layers of nonwoven polypropylene). The mask is a single use, disposable device, provided nonsterile.
The mask is in accordance to ASTM F2100 Level 3.
The proposed device is not made from natural rubber latex

5. Indications for Use:

The Impertech Surgical Face Mask are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluid. This is a single use, disposable device, provided non-sterile.

6. **Comparison to the 510(k) Cleared Devices (Predicate Devices):**

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Impertech Surgical Face Mask	Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask	Similar
510(k) Reference	K212046	K202595	Similar
Product Owner	Impertech Industries Ltd.	Premier Guard USA LLC	Similar
Product Code	FXX	FXX	Same
Indications for Use	The Impertech Surgical Face Mask are intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s) provided non-sterile.	The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Masks are intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s) provided non-sterile.	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Mask Style	Flat Pleated, Ear Loops, 3 Layers	Flat Pleated, Ear Loops, 3 Layers	Same
Mask Color	White	Blue	Similar
Materials			
Nose Piece (material)	Polypropylene laminated soft annealed carbon steel wire	Polyethylene laminated soft annealed carbon steel wire	Same
Ear Loops (material)	Nylon and Spandex	Nylon and Spandex	Same
Outer Facing Layer	Spunbond polypropylene	Spunbond polypropylene	Same

Middle Layer	Melt blown fiber	Melt blown fiber	Same
Inner Facing Layer	Spunbond polypropylene	Spunbond polypropylene	Same
Dimensions - Width	175 mm	175 mm	Same
Dimensions - Length	95 mm	95 mm	Same
ASTM F2100 Level	Level 3	Level 3	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic	Under the conditions of the study, the device is noncytotoxic	Same
Sensitization	Under the conditions of the study, the device is nonsensitizing	Under the conditions of the study, the device is nonsensitizing	Same
Irritation	Under the conditions of the study, the device is nonirritating	Under the conditions of the study, the device is nonirritating	Same
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same

Discussion of Similarities and Differences between subject device and predicate device:

The subject Impertech Surgical Face Mask subject device surgical mask and the Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask predicate device are same with all the parameters except for the color of the mask. The color of the subject device mask is without Color (white) whereas the predicate device is blue in color. The change in the color of the mask between the subject device and the predicate device does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device.

None of the biocompatibility testing or performance testing results demonstrated any safety hazards or any design characteristics that violated the requirements set forth in the Guidance for Industry regarding Premarket Notification Submissions of Surgical Masks

7. **Non-Clinical Performance Testing**

The Impertech Surgical Face Mask was tested in accordance with the tests recommended in the FDA guidance document, Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has been performed.

- Fluid Resistance per ASTM F1862
- Particulate Filtration Efficiency per ASTM F2299
- Bacterial Filtration Efficiency per ASTM F2101
- Differential Pressure (Delta P) per EN 14683
- Flammability per 16 CFR 1610

Performance Testing		
Surgical Mask Characteristics – ASTM F2100	**Level 3 Barrier**	**Result**
Bacterial filtration efficiency %	≥98	Pass
Differential pressure, mm H2O/cm²	<6	Pass
Sub-micron particulate filtration efficiency at 0.1 micron %	≥98	Pass
Resistance to penetration by synthetic blood, minimum press in mm Hg for pass result	160	Pass
Flammability	Class I	Pass

Performance Testing (Animal)

The biocompatibility evaluation for the Impertech Surgical Face Mask was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Impertech Surgical Face Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

Biocompatibility Evaluation				
	Bilogical Effect	**Standard**	**Results**	
1	Cytotoxicity	ISO 10993-5	Not cytotoxic	Pass
2	Sensitization	ISO 10993-10	Non sensitizing	Pass
3	Irritation	ISO 10993-10	Negligibly irritating	Pass

8. **Clinical Performance Testing**

Not Applicable

9. Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device, K202595 Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask.