March 30, 2021

Intco Medical(HK) Co., Ltd.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K202708
Trade/Device Name: Surgical Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 19, 2021
Received: March 22, 2021

Dear Prithul Bom:

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 Ryan Ortega, PhD
Acting 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)*
K202708

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
Surgical Face Masks 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 of the wearer to blood and body fluids. This is a single use, disposable device(s), 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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INTCO Medical (HK) Co., Ltd.

Flat/RM 19c, Lockhart Centre 301-307 Lockhart road, Wan Chai, Hong Kong

K202708

510(K) SUMMARY

1. **Submitter's Identification:**

   INTCO Medical (HK) Co., Ltd.
   Flat/RM 19c, Lockhart Centre 301-307 Lockhart road,
   Wan Chai, Hong Kong

   Contact Person:
   Max Li
   Product Manager
   Phone number: 86-511-83174088
   Fax: 86-511-83174188
   Email: maxli@intco.com

   Date summary prepared:
   March 30, 2021

2. **Device Name:**
   Surgical Face Masks
   Trade Name:
   Surgical Face Mask

3. **Device Classification Name:**
   Mask, Surgical (21 CFR 878.4040)
   Device Classification Panel:
   General Hospital

4. **Device Class:**
   Class II

5. **Product Code:**
   FXX Mask, Surgical

6. **Predicate Device:**
   - Zhende Medical Co., Ltd.
     Medical Mask(K201729)

7. **Reason for 510(k) Submission:**
   New device.

8. **Device Description:**
   Surgical Face Masks 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 of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

   The surgical face masks are single use multi-layer masks with outer layer and inner layer of polypropylene spunbond that sandwich a meltblown polypropylene filter material. The surgical face mask includes malleable aluminum nosepiece that can be bent to contour the nose. The surgical face masks are held in place with ear loops made of polyester/Lycra.

9. **Intended Use/Indications for Use:**
   Surgical Face Masks 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 of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

10. Comparison between the device and predicate device:

Feature	(Proposed Device) Surgical Face Masks	(Predicate Device) K201729	Remarks
510(K) #	Proposed Device K202708	K201729	Proposed device is same as or similar to the primary predicate
Manufacturer	INTCO Medical (HK) Co., Ltd.	Zhende Medical Co Ltd.	NA
Common Name	Surgical Face Mask	Medical Mask	Common name of the proposed device is similar to the predicate device
Classification	Class II	Class II	Device class of the proposed device is the same as the predicate device
Product Code	FXX	FXX	Product code of the proposed device is the same as the predicate device
Intended Use	Surgical Face Masks 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 of the wearer to blood and	The Medical Masks 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 of the wearer to blood and body fluids. This is a	The intended use of the proposed device is the same as the predicate device.

	body fluids. This is a single use, disposable device(s), provided non-sterile.	single use, disposable device(s), provided non-sterile.	
Materials			
Outer Layer	Polypropylene Spunbond Color: Blue	Spun-bond Polypropylene Color: Blue	Materials of the proposed device are the same as or similar to the predicate device
Inner Layer	Polypropylene Spunbond	Spun-bond Polypropylene	
Filter Media Layer	Polypropylene Meltblown	Melt Blown Polypropylene filter	
Ear Loops	Ear loops: Polyester/lycra knitted Diameter: 0.3 cm Length: 17.5 cm.	Ear loops: Polyester/Spandex	
Nosepiece	Malleable aluminum strip Width: 0.3 cm Length: 10 cm	Malleable polypropylene with iron wire	
Specifications and Dimensions	Length: 165 ± 19 mm Width: 102 ± 19 mm	Length: 180 ± 10 mm Width: 95 ± 10 mm	Specifications and dimensions of the proposed device are similar to the predicate device
Mask Style	Flat pleated	Flat pleated	The mask style of the proposed device is the same as the predicate device

Sterility	Non-sterile	Non-sterile	The proposed product and predicate device are non-sterile.
ASTM F2100 Level	Level 1	Level 1	The proposed product and predicate device have the same ASTM F2100 Level
Performance Testing (Completed)			
Fluid Resistance	Fluid Resistant at 80 mmHg Lot 20201013 31/32 Passed 80 mmHg Lot 20201022 32/32 Passed 80 mmHg Lot 20201105 32/32 Passed 80 mmHg ASTM F1862	Fluid Resistant at 80 mmHg ASTM F1862	Fluid resistant performance of the proposed device is the same as the predicate device
Particulate Filtration Efficiency (PFE)	Lot 20201013 32/32 PASSED 99.866% Lot 20201022 32/32 PASSED 99.9784% Lot 20201105 32/32 PASSED 99.9879% ASTM F2299	$\geqslant$ 95% ASTM F2299	Particulate Filtration Efficiency performance of the proposed device is similar to the predicate device
Bacterial Filtration Efficiency (BFE)	Lot 20201013 32/32 PASSED 99.9% Lot 20201022 32/32 PASSED 99.9% Lot 20201105 32/32 PASSED 99.9% ASTM F2101	$\geq$ 95% ASTM F2101	Bacterial Filtration Efficiency performance of the proposed device is similar to the predicate device
Differential Pressure	< 5.0mmH_2O/cm^2 Lot 20201013 Average 3.9 mmH_2O/cm^2 Lot 20201022	< 5.0mmH_2O/cm^2 EN 14683 Annex C	Differential Pressure performance of the proposed device is the same as the predicate device.

	Average 3.9 mmH_2O/cm^2 Lot 20201105 Average 4.2 mmH_2O/cm^2 EN 14683 Annex C		
Flammability	Class 1 Lot 20201013 IBE Lot 20201022 IBE Lot 20201105 IBE 16 CFR 1610	Class 1 16 CFR 1610	Flammability performance of the proposed device is the same as the predicate device
Biocompatibility	Under the conditions of the study, the device is non-cytotoxic ISO 10993-5 Under the conditions of the study, the device is non-sensitizing ISO 10993-10 Under the conditions of the study, the device is non-irritating ISO 10993-10	No cytotoxicity ISO 10993-5 No sensitization ISO 10993-10 No Irritation ISO 10993-10	Biocompatibility performance of the proposed device is the same as the predicate device

11. Non-Clinical Tests Performed

ASTM 2100, Standard Specification for Performance of Materials Used in Medical Face Masks

ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Syntehtic Blood (Horizontal Projection of Fixed Volume At A Known Velocity);

ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;

ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus;

EN 14683 Annex C, Medical Face Masks – Requirements and Test Methods;

16 CFR 1610, Standard for Flammability of clothing textiles;

ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity

ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation And Skin Sensitization

12. Clinical Test Performed

No clinical testing was performed.

13. **Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202708, FXX, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201729.