December 2, 2021

Taiwan Seafood and Fish Corporation
Eric Ly
Business Development Assistant
733 Gladys Avenue
Los Angeles, California 90021

Re: K211773
Trade/Device Name: Single-use Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 26, 2021
Received: September 1, 2021

Dear Eric Ly:

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)*
K211773

Device Name
Single-Use Surgical Mask

Indications for Use *(Describe)*
The Single Use Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. This is a single use 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
K211773

1. Submitter Information

Submitted by:	Taiwan Seafood and Fish Corporation 733 Gladys Avenue Los Angeles, CA 90021 213-624-2927
Date Prepared:	11/18/2021
Contact Person:	Eric Ly Business Development Assistant erickltsf@gmail.com

2. Subject Device

Proprietary Name:	Single-Use Surgical Mask
Common Name:	Surgical Face Mask
Classification Name and Reference:	21 CFR 878.4040, Class II
Device Product Code, Device Panel:	FXX, General Hospital

3. Predicate Device

Predicate Device 510(k) Number:	K202824
Submitter:	Blackbriar Regulatory Services, LLC
Proprietary Name:	BRS Procedure Face Mask
Device Product Code:	FXX
Regulation:	21 CFR 878.4040

4. Device Description

The Single-Use Surgical Mask is a 3-ply, disposable surgical face mask. The outer and inner layers of the mask are made of spunbond polypropylene, while the middle layer consists of a meltblown polypropylene filter fabric. The device is secured on the user's face via elastic earloops and are labeled non-sterile, single-use, and disposable. This device is a surface device intended to come in contact with intact skin for a duration of less than 24 hours.

5. Indications for Use

The Single Use Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. This is a single use device provided non-sterile.

The Indications for Use statement for the Single-Use Surgical Mask is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the protection of both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

6. Comparison of Technological Characteristics

The Single-Use Surgical Mask is made of an outer layer consisting of spunbond polypropylene fabric, a middle layer of meltblown polypropylene filter, an inner layer of spunbond polypropylene, 2 earloops made out of nylon and spandex, and a polyethylene nose wire. The technological characteristics of this device are similar to the predicate device because the materials are similar or identical.

Item	**Subject Device**	**Predicate Device**	**Comparison**
510(k) Number	K211773	K202824	-
Trade Name	Single-Use Surgical Mask	BRS Procedure Face Mask	-
Indications For Use	The Single Use Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. This is a single use device provided non-sterile.	BRS Procedure Face Mask is a non-sterile, single use, disposable face mask intended to be worn to protect both healthcare personnel and patients from the transfer of microorganisms, blood and body fluids, and particulate material. This equipment is intended for the use in infection control practices to reduce the potential exposure to blood and fluids. BRS Level 1 Procedure Face Mask (Model# 00850021617004)	Similar
Materials	Outer Layer: Spunbond polypropylene Middle Layer: Meltblown polypropylene filter Inner Layer: Spunbond Polypropylene Earloop: Spandex and Nylon Nose piece: Polyethylene wire	Outer Layer: Spunbond polypropylene Middle Layer: Meltblown polypropylene filter Inner Layer: Spunbond polypropylene Earloop: Spandex and Nylon Nosepiece: iron wire covered in plastic	Similar
Mask Style	3-ply, disposable, non-sterile	3-ply, disposable, nonsterile	Same
Mask Dimensions	175mm x 95mm	175mm x 95mm	Same
ASTM F2100 Level	Level 1	Level 1 variant	Similar
Biocompatibility (ISO 10993-5, 10)	Under the conditions of study, non-cytotoxic, non-irritating, and non-sensitizing	Under the conditions of study, non-cytotoxic, non-irritating, and non-sensitizing	Same

The subject device meets the same ASTM F2100 requirements as the ASTM F2100 Level 1 variant of the predicate device.

7. Summary of Nonclinical Testing

Item/Test Method	Purpose	Criteria	Result
Fluid Resistance (mmHg) (ASTM 1862)	Demonstrate resistance to fluid spray	Pass at 80 mmHg (level 1 fluid resistance)	Pass
Bacterial Filtration Efficiency (%) (ASTM F2101-19)	Demonstrate resistance to bacterial penetration	Pass at ≥ 99%	Pass

Particulate Filtration Efficiency (%) (ASTM F2299)	Demonstrate resistance to penetration of particulate matter	Pass at ≥ 95%	Pass
Differential Pressure (EN 14683)	Demonstrate breathability	Pass at < 5.0 mm H_2O/cm^2	Pass
Flammability (16 CFR 1610)	Demonstrate low flammability	Class 1	Pass
Biocompatibility: Cytotoxicity (ISO 10993-5)	Demonstrate low cytotoxic potential	Under the conditions of the study, non-cytotoxic	Pass
Biocompatibility: Skin sensitization (ISO 10993-10)	Demonstrate low skin sensitization potential	Under the conditions of the study, not a sensitizer	Pass
Biocompatibility: Skin Irritation (ISO 10993-10)	Demonstrate low skin irritation potential	Under the conditions of the study, not an irritant	Pass
ASTM F2100 Level (ASTM F2100)	Demonstrates face mask performance	Meet Level 1 requirements	Pass

8. Clinical Testing

No clinical testing is included in this submission.

9. Conclusion

The conclusions from the non-clinical testing demonstrate that the Single Use Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, BRS Level 1 Procedure Face Mask (K202824).