September 2, 2022

Savewo Limited
℅ Ivy Lai
Regulatory Manager
Long Jing Technology Ltd.
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong 0000
China

Re: K221957
Trade/Device Name: Savewo ClassicMASK
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 1, 2022
Received: July 5, 2022

Dear Ivy Lai:

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
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221957

Device Name
Savewo ClassicMASK

Indications for Use *(Describe)*
Savewo ClassicMASKs are intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.
Savewo ClassicMASKs 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) and 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.

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510(k) Summary

1 Date Prepared

06/30/2022

2 Submitter's Information

Name of Sponsor: Savewo Limited

Address: 1/F & 2/F, 266-270 Texaco Road, Tsuen Wan, Hong Kong

Contact Name: Melanie Choi

Telephone No.: +852 5503 2370

E-mail: melanie@savewo.com

3 Trade Name, Common Name, Classification

Trade/Device Name: Savewo ClassicMASK

Common Name: Surgical face mask

Classification Name: Surgical apparel

Review Panel: General and Plastic Surgery

Product Code: FXX

Device Classification: 2

4 Identification of Predicate Device(s)

Predicate Device: Single-use Surgical Mask (K200923)

5 Description of the Device

Savewo ClassicMASK is a 3-layered mask. The outer layer is made of spunbond polypropylene with white color, the inner layer is made of hydrophilic polypropylene/polyethylene non-woven fabric, and the middle layer with filtration function is made of melt-blown polypropylene. The

mask contains ear loops to secure the mask over the users' mouth and face and the metal nose strip over the top edge which secures the mask to stay firmly in place. Savewo ClassicMASK is single use, disposable, non-sterile and ASTM Level 3 certified.

6 Indication

Savewo ClassicMASKs are intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.

Savewo ClassicMASKs 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) and provided non-sterile.

7 Comparison to the Predicate Device

Savewo ClassicMASK, the subject of this application, is compared with the predicate Device, Single-use Surgical Mask (K200923), in terms of indication, mechanism, design features, structure/material, and performance. The subject device and predicate devices claim Level 3 in accordance with ASTM F2100-19 standard.

The results are shown below in the Technological Characteristics Comparison Table:

	Subject Device	**Predicate Device**	**Comparison**
Manufacturer	Savewo Limited	BYD Precision Manufacturer Co.Ltd.	
Trade Name	Savewo ClassicMASK	Single-use Surgical Mask	
510(k) number	N/A	K200923	--
Device Class	2	2	Same
Product Code	FXX	FXX	Same
Device classification Name	Surgical apparel	Surgical apparel	Same
Regulation number	878.4040	878.4040	Same
Intended Use/ Indications for Use	Savewo ClassicMASKs are intended to be worn to protect both patient and	The Single-use Surgical Masks (Model: FE2311) are intended to be worn	Same

	healthcare personnel from transfer of microorganisms, body fluids, and particulate material. Savewo ClassicMASKs 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) and provided non-sterile.	to protect both thepatient and healthcare personnel from transfer of microorganisms, body fluids and particulatematerial. These face masks are intended for use in infection control practices to reduce thepotential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Materials			
Outer cover web	Spunbond Polypropylene	Spunbond polypropylene	Same
Middle web	Melt-Blown Polypropylene	Melt-blown polypropylene filter	Same
Inner cover web	50% polypropylene + 50% polyethylene Hydrophilic non-woven fabric	Spunbond polypropylene	Different[*1]
Nose wire	75% polypropylene + 25% iron nose-strip	Metal Core Plastic	Different[*1]
Ear loop	80% polyamide + 20% spandex ear-loop	Polyester	Different[*1]
Design Features			
Colors	White	Blue	Different[*2]
Style	Flat-pleated	Flat Pleated	Same
Multiple layers	3 layers	3 layers	Same
Single use	Yes	Yes	Same
Dimensions	175x95 mm	175x95 mm	Same
Sterility			
Sterile	Non-Sterile	Non-Sterile	Same
Biocompatibility			
Cytotoxicity	Non-Cytotoxic	Non-Cytotoxic	Same
Sensitization/irritation	Non-sensitizing, Non-irritating	Non-sensitizing, Non-irritating	Same
Product barrier specification ASTM F2100 - Meets ASTM Level 3			
Bacterial filtration efficiency (BFE) (%) ASTM F2101	Passed at ⩾98%	Passed at ⩾98%	Same
Particulate filtration efficiency (PFE) (%) ASTM F2299	Pass at ⩾98% @ 0.1 micron	Pass at ⩾98% @ 0.1 micron	Same
Differential pressure (mmH_2O/cm^2) MIL-M36954C	Passed at <6 mmH_2O/cm^2	Passed at <6 mmH_2O/cm^2	Same
Resistance to penetration by synthetic blood (mmHg)	Passed at 160mm Hg	Passed at 160mm Hg	Same

ASTM F1862			
Flammability CFR 16 1610	Class 1	Class 1	Same
*1: The differences in the materials of inner layer, nose wire and ear loop do not raise additional questions for safety and effectiveness. Biocompatibility evaluation has been performed on the finished device which includes all construction materials. Besides, the subject device conforms with ASTM F2100 standard and meets level 3 performance specifications. *2: The difference in the color does not raise additional questions for safety and effectiveness because they are only used in the outer layer of the mask. Biocompatibility evaluation has been performed on the finished device which includes all construction materials.			

The Savewo ClassicMASK has same indications, same mechanism, similar materials, similar product design, same performance as the predicate devices. The Savewo ClassicMASK is substantially equivalent to the Single-use Surgical Mask (K200923) as these products conform with ASTM F2100 standard and meet Level 3 performance specifications. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device.

8 Non-Clinical Testing Summary

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

a) Biocompatibility

Item	Test Mothd/ Standard	Acceptance Criteria	Results
Cytotoxicity	ISO 10993-5:2009 – Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity	Non-Cytotoxic	Pass
Sensitization	ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization	Non-sensitizing	Pass
Irritation	ISO 10993-10:2010 – Biological Evaluation of Medical Devices -- Part 10: Tests for Irritation and Skin Sensitization	Non-irritating	Pass

b) Performance test

Item	Test Method/ Standard	Acceptance Criteria	Results
Bacterial filtration efficiency (BFE) (%)	ASTM F2101-19 - Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	Passed at ⩾ 98%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: ⩾99.9% Lot 2: ⩾99.9% Lot 3: ⩾99.9%
Particulate filtration efficiency (PFE) (%)	ASTM F2299/F2299M-03 - Standard Test Method for Determining the Ini-tial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	Pass at ⩾98%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: ⩾99.6% Lot 2: ⩾99.7% Lot 3: ⩾99.7%
Differential pressure (mmH_2O/cm^2)	MIL-M-36945C, Military Specifications: Surgical Mask, disposable	Passed at <6 mmH_2O/cm^2	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: <4.11 mmH_2O/cm^2 Lot 2: <4.19 mmH_2O/cm^2 Lot 3: <4.08 mmH_2O/cm^2
Resistance to penetration by synthetic blood (mmHg)	ASTM F1862/F1862M-17 - Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Passed at 160mm Hg	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 32 out of 32 Pass at 160 mmHg Lot 2: 31 out of 32 Pass at 160 mmHg Lot 3: 31 out of 32 Pass at 160 mmHg
Flammability	16 CFR Part 1610 - Standard for the Flammability of Clothing Textiles	Class 1	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1

a) Accelerated aging test

- ASTM F1980-16 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

b) Transportation test

- ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems

9 Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Savewo ClassicMASK is as safe, as effective, and performs as well as or better than the legally marketed predicate device Single-use Surgical Mask (K200923).