June 10, 2021

Sample King Manufacturing Ltd
Forest Cao
QC Manager
Southwest side of the intersection of Mingzhu Boulevard and
Shenyan Road, Yantian District
Shenzhen, Guangdong 518083
China

Re: K210015
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 30, 2021
Received: May 3, 2021

Dear Forest Cao:

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,

Clarence W. Murray, III, 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)*
K210015

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The surgical face mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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.

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.

510(K) Summary

This summary of 510(K) is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 510(K) number is: K210015

1. **Submitter Information**:

Name: Sample King Manufacturing Ltd
Address: 1001# 1st floor and 4011# 4th floor of HESC Building, southwest side of the intersection of Mingzhu Boulevard and Shenyan Road, Yantian District, 518083, Shenzhen, China

Contact Person: Ms. Forest Cao
Position: Manager
Tel : 0086-0755-33095566 Fax : 0086-0755-33095565
Email: forest.cao@sampleking.com

Date of 510(k) Summary Prepared:2020-12-29

2. **Device Information**

Trade/Common Name: Surgical Face Mask
Models: Ear loop type, 17.5cm×9.5cm
Regulatory Class: Class II
Regulatory Number: 21 CFR 878.4040
Review Panel: General Hospital
Product Code: FXX (Mask, Surgical)

3. **Predicative Device**

Manufacturer: WUHAN DYMEX HEALTHCARE CO., LTD
Device Name: Surgical Face Mask
Model(s): Ear Loop
510(k) Number: K182515

4. **Device Description:**

Surgical Face Mask is composed of a mask body, a nose clip, and two ear ropes.
The mask body of ear loop type has three layers in structure: the inner and outer layers are made of polypropylene non-woven fabrics, and the middle layer is made of polypropylene melt-blown cloth. The component ratio is 24.5% melt blown cloth and 71.5% PP non-woven.

The nose clip contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of PE.
The ear ropes are made of nylon and spandex.
This is a single use, disposable device(s), provided non-sterile.

5. Indication for Use

The surgical face mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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.

6. Technological Characteristic Comparison Table

Provided below is a comparison of the proposed device with predicate device.

Table 1 Comparison of Technological characteristics

Item		Proposed device	Predicate Device	Comparison
Manufacturer		Sample King Manufacturing Ltd	WUHAN DYMEX HEALTHCARE CO., LTD	/
510(k) Number		K210015	K182515	/
Product name		Surgical Face Mask	Surgical Face Mask	Same
Product Code		FXX	FXX	Same
Indication for Use		The surgical face mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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 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 to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Model		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Color		Blue and White	Yellow	**Different**
Materials	Inner and Outer Layers	Blue PP non-woven（Outer Layers） White PP non-woven （Inner Layers)	Spun-bond polypropylene	Similar

	Middle Layer	White melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Ear ropes	Nylon+spandex	Spandex	Similar
	Nose clip	Malleable polyethylene wire	Malleable polyethylene wire	Same
Sterile		Non-sterile	Non-sterile	Same
Dimensions		17.5cm×9.5cm	17.5cm×9.5cm	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 3	Level 2	**Different**

7. Summary of Non-clinical Performance Testing

Non-clinical tests were conducted 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 05, 2004.

Item	**Standard**	**Acceptance Criteria**	**Results**
Fluid Resistance Performance （mmHg）	ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	At least 29 out of 32 specimens show passing results at 160 mmHg	Total 3 lots 96/96. All samples met the predetermined acceptance criteria.
Particulate Filtration Efficiency Performance (%)	ASTM F2299 / F2299M - 03(2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	≥ 98%	99.6%， total 3 lots 95 out of 96 samples met the predetermined acceptance criteria.

Bacterial Filtration Efficiency Performance (%)	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	≥ 98%	>99.9%, total 3 lots 96/96 All samples met the predetermined acceptance criteria.
Differential Pressure (Delta-P) (mm H2O/cm2)	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	< 6.0 mm H_2O/cm^2	2.2- 3.3 mm H_2O/cm^2, total 3 lots 96/96. All samples met the predetermined acceptance criteria.
Flammability	21 CFR 1610	Class I	Total 3 lots 96/96 Did Not Ignite. All samples met the predetermined acceptance criteria.
Cytotoxicity	ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic	All samples met the predetermined acceptance criteria.
Irritation	ISO 10993-10: Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization	Non-irritating	All samples met the predetermined acceptance criteria.
Sensitization	ISO 10993-10: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Non-sensitizing	All samples met the predetermined acceptance criteria.

8. Clinical performance Data

No clinical study is included in this submission.

9. Conclusion:

The conclusions drawn from the nonclinical test demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.