December 24, 2021

Control Print Limited
% Manoj Zacharias
US Agent
Liberty Management Group Ltd.
75 Executive Drive, Suite 114
Aurora, Illinois 60504

Re: K213136
Trade/Device Name: CPL Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 20, 2021
Received: September 27, 2021

Dear Manoj Zacharias:

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
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)*
K213136

Device Name
CPL Surgical Face Mask

Indications for Use *(Describe)*
The 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. The face masks are intended for use in infection control practices to reduce the potential exposure to blood & body fluid. This device is disposable, non-sterile and for single use only.

Available models:
Surgical Face Mask EL (Ear loops)
Surgical Face Mask TO (Tie-on)

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 (K213136)

[AS REQUIRED BY 21CFR807.92]

I. APPLICANT INFORMATION

Submitter's Name	Control Print Limited
Submitter's Address	Village Bhatian, Near TVS Factory, Bharatgarh Road, Nalagarh, District Solan -174101, Himachal Pradesh, India
Name of Contact Person	Mr. Pankaj Sharma
Designation	Manager Quality Assurance
Division Name of Contact Person	Quality Management
Contact Number	91 9805020592
Contact E-mail	nalagarhqm@controlprint.com
Date of Summary Prepared	22 December 2021

II. DEVICE DETAILS

Device Trade Name	CPL Surgical Face Mask
Device Common Name	Surgical Face Mask
Model(s)	Surgical Face Mask EL, Surgical Face Mask TO
Device Classification name	Mask, Surgical
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

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HYDERABAD • JAMSHEDPUR • KERALA • KOLKATA • NEPAL • PUNE

III. PREDICATE DEVICE DETAILS

Device Trade Name	Disposable Surgical Face Mask
Device Manufacturer Name	Anhui Jiabao Protective Equipments Co., Ltd
Model(s)	JB-DMO3 (Ear Loops), JB-DMO4 (Tie on)
510(k) Number	K203801
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

IV. DEVICE DESCRIPTION

The CPL Surgical Face Mask is a 3-ply flat-pleated mask. The inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The nose wire 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 polypropylene coated single core galvanized wire.

The model Surgical Face Mask EL is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The ear loops are made of braided elastic band. The model Surgical Face Mask TO is provided with non-woven tie-on string.

The dimensions of the test item are: length- 175 ± 5 mm and width- 95 ± 5 mm. The ear loop length of the model Surgical Face Mask EL is 170± 5 mm. The tie-on of the model Surgical Face Mask TO has a top strap length of 410 ± 10 mm and bottom strap length of 385 ± 10 mm.

The surgical masks are single-use, disposable devices, provided non-sterile.

V. INTENDED USE

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non sterile and for single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K213136	K203801	-
2.	Manufacturer	Control Print Limited	Anhui Jiabao Protective Equipments Co., Ltd	-
3.	Common Name	Surgical face mask	Surgical face mask	Same
4.	Classification Name	Mask, Surgical	Mask, Surgical	Same
5.	Classification and Regulation number	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Same
6.	Product Code	FXX	FXX	Same
7.	Indications For Use	The surgical face mask are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluidsand particulate material. The face masks are intended for use in infection control practices to reduce the potential exposure to blood & body fluid. This device is disposable, non-sterile and for single use only. Available models: **Surgical Face Mask EL** (Ear loops) **Surgical Face Mask TO** (Tie-on)	The Disposable Surgical Face Mask is 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 a single use, disposable device(s), provided non-sterile.	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
8.	Model specifications	Surgical Face Mask EL(3 ply flat-pleated masks with ear loops) Surgical Face Mask TO (3 ply flat-pleated masks with tie-on)	JB-DM03(Ear Loops, Flat Pleated, 3 layers) JB-DM04(Tie-On, Flat Pleated, 3 layers)	Same
Materials				
9.	Outer layer	Spun bond polypropylene	Spun bond polypropylene	Same
10.	Filter layer	Melt blown polypropylene	Melt blown polypropylene filter	Same
11.	Inner layer	Spun bond polypropylene	Spun bond polypropylene	Same
12.	Nose wire	Polypropylene coated single core galvanized wire	PE and iron	Different[1]
13.	Ear loop/ Tie-on	**For model: Surgical Face Mask EL** Ear Loop: Braided Elastic Band **For model: Surgical Face Mask TO** Tie-on: Non-woven tie-on string	**For model: JB-DM03** Ear Loop: Nylon and spandex **For model: JB-DM04** Tie-on: Spun-bond polypropylene	Different[2]
14.	Mask color	Blue	Blue	Same
15.	Dimensions	Length- 175 ± 5 mm Width- 95 ± 5 mm **For model: Surgical Face Mask EL** Ear Loop Length: 170± 5 mm **For model: Surgical Face Mask TO** Tie-on strap length - Top: 410 ± 10 mm - Bottom : 385 ± 10 mm	Length- 175 ± 5 mm Width- 95 ± 5 mm	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
16.	OTC Use	Yes	Yes	Same
17.	Sterility	Non-sterile	Non-sterile	Same
18.	Reusability	Single use	Single use	Same
19.	ASTM F2100 Level	Level 3	Level 2 & 3	Similar

Non Clinical Testing						
Tests Performed		**Model No.: Surgical Face Mask EL**	**Model No.: Surgical Face Mask TO**	**Model No.: JB-DM03 (Ear loop model)**	**Model No.: JB-DM04 (Tie-on model)**	**Result**
20.	Fluid resistance	Pass at 160 mmHg	Pass at 160 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Different[3]
21.	Flammability	Class 1	Class 1	Class 1	Class 1	Same
22.	Particulate Filtration Efficiency (PFE)	≥ 98%	≥ 98%	≥ 98%	≥ 98%	Same
23.	Bacterial Filtration Efficiency (BFE)	≥ 98%	≥ 98%	≥ 98%	≥ 98%	Same
24.	Differential pressure (ΔP)	< 6.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	Same
25.	Biocompatibility Testing	No potential cytotoxicity Non-irritating Non-sensitizing	No potential cytotoxicity Non-irritating Non-sensitizing	No potential cytotoxicity Non-irritating Non-sensitizing	No potential cytotoxicity Non-irritating Non-sensitizing	Same

VII. JUSTIFICATION FOR DIFFERENCES

The difference is mainly observed in the nose strip, ear loop/tie-on and ASTM F2100 level of ear loop model. The differences between proposed device and the predicate device are discussed in detail below and the justifications are included:

Different(1): The proposed device is using nose wire of polypropylene coated single core galvanized wire whereas the predicate device is using nose wire made of PE and iron.

Different(2): In the proposed device, for model Surgical Face Mask EL, ear loop is made of braided elastic band. But, in the predicate device, for model JB-DM03, the ear loop is made of nylon and spandex. The proposed device model Surgical Face Mask TO is provided with non-woven tie-on string whereas in the predicate device model JB-DM04 the tie-on is made of spun-bond polypropylene.

Different(3): The proposed device model Surgical Face Mask EL has passed the acceptance criteria for level 3 whereas the predicate device model JB-DM03 has passed the acceptance criteria for level 2 as per ASTM F2100.

VIII. PERFORMANCE DATA

A. Non- Clinical Data

Performance Tests

CPL Surgical Face Mask is subjected to the following performance tests according to the requirements provided in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions** :

- Fluid resistance
- Bacterial filtration efficiency
- Particulate filtration efficiency
- Differential pressure
- Flammability

The performance testing of the proposed device was conducted using 3 nonconsecutive lots to demonstrate that it meet the acceptance criteria and specification in the method shown below:

ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

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.

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

EN 14683 (Annex C): 2019 Medical Face Masks – Requirements And Test Methods

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)

16 CFR 1610 Standard for the Flammability of clothing textiles

Table 2: Performance Testing Summary

Sl. No	Test Performed	Proposed Device		Acceptance criteria for Level 3 Classification as per ASTM F2100 Requirements	Result
		Model No. : Surgical Face Mask EL	Model No. : Surgical Face Mask TO		
1.	Fluid resistance ASTM F1862/ F1862M-17	Pass at 160 mmHg	Pass at 160 mmHg	Pass at 160 mmHg	Pass
2.	Particulate Filtration Efficiency (PFE) ASTM F2299 / F2299M - 03(2017)	>98%	>98%	≥ 98%	Pass
3.	Bacterial Filtration Efficiency (BFE) ASTM F2101-19	> 98%	> 98%	≥ 98%	Pass
4.	Differential pressure (ΔP) EN 14683 (Annex C): 2019	< 4.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	Pass
5.	Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Pass

Biocompatibility

The materials used in the CPL Surgical Face Mask are biocompatible based on the biocompatibility tests mentioned in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions**:

- In-vitro Cytotoxicity
- Skin irritation
- Skin Sensitization

These tests are performed according to **ISO 10993-1:2018**, Biological Evaluation of Medical Devices - Part 1, Evaluation and Testing within a Risk Management Process.

The biocompatibility testing of the proposed device was conducted to adequately demonstrate the safety of the device in accordance with the relevant methods cited below:

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.

Table 3: Biocompatibility Test Summary

Sl. No	Test Performed	Standard	Proposed Device		Result
			Model No. : Surgical Face Mask EL	Model No. : Surgical Face Mask TO	
1.	In-vitro Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Non-cytotoxic	Pass
2.	Skin Irritation	ISO 10993-10:2010	Non-irritating	Non-irritating	Pass
3.	Skin Sensitization	ISO 10993-10:2010	Non-sensitizing	Non-sensitizing	Pass

B. Clinical Test Data

Clinical study was not conducted as clinical data is not needed for surgical mask.

IX. CONCLUSION

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