September 16, 2022

Allure Gift Wraps Private Limited
% Sharad Raisinghani
US Agent
Allure Life Sciences LLC
4Hancock CT, Basking Ridge,
New Jersey, New Jersey 07920

Re: K212926
Trade/Device Name: Allure™ Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 15, 2022
Received: August 25, 2022

Dear Sharad Raisinghani:

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)*
K212926

Device Name
ALLURETM Surgical Mask

Indications for Use *(Describe)*

ALLURETM Surgical 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.

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-K212926

Device Name- ALLURE™ Surgical Mask

5.1 Submission Sponsor Information [21 CFR 807.929(a) (1)]

Allure Gift Wraps Pvt Ltd
Plot No. J 21, J type area,
1st Phase GIDC Vapi,
396195 Vapi,
India
Cell Phone Number**:** 91-9819837267
E-mail**:** sharad@allurewraps.com
Website: https://allurewraps.com
Primary Contact: Mr Mohan Raisinghani
Secondary Contact: Mr Sharad Raisinghani

5.2 Date Prepared

15th September 2022

5.3 Device Identification [21 CFR 807.92(a) (2)]

Trade/Proprietary Name:	ALLURE™ Surgical Mask
Classification Name:	Mask, Surgical
Regulation Name:	Surgical apparel
Regulation Number:	21 CFR 878.4040
Product Code:	FXX
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

5.4 Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a) (3)]

Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G,
Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G by KCI USA Inc. by BH Medical Products Co., Ltd. (K133070)

Traditional 510(k) Premarket Submission.
ALLURE™ Surgical Mask

5.5 Device Description [21 CFR 807.92(a) (4)]

ALLURE™ Surgical mask is valve less, consisting of 5 layers made up of breathable PP non-woven, hot air insulation cotton, two layers of melt blown fabrics, non-woven fabrics and plastic nose strips and Elastic cord. The device is designed and tested as per its device specific guidance; “Surgical Masks-Premarket Notification 510(k) Submissions".

Figure 5.1: ALLURE™ Surgical Mask (Flat type Mask)

Duration and type of contact: Direct contact, less than 24 hours, skin contact
Single use disposable device: Yes
Sterile: No

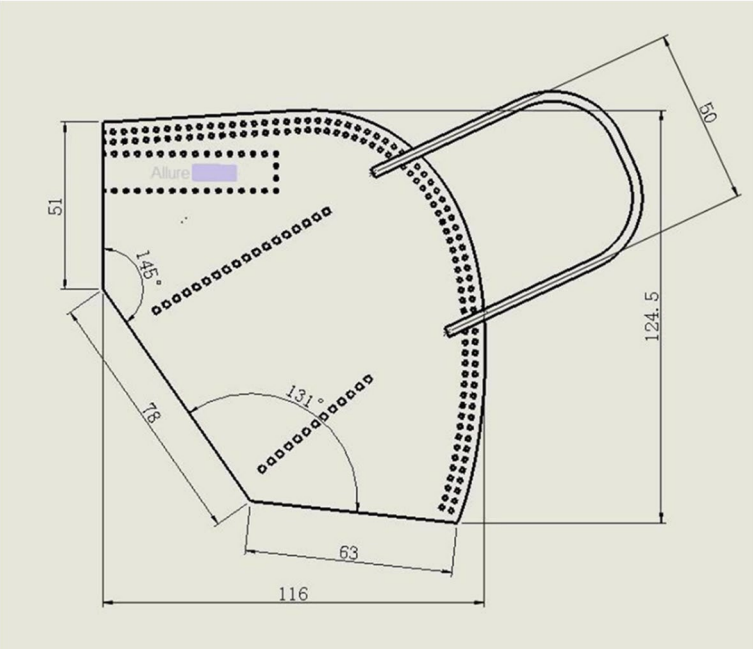
Size of Mask: **Dimension (length):** 155 ± 5 mm

Dimension (width): 105 ± 5 mm

User Profile/Population: Adults

ASTM Level: ASTM Level 1

Use Environment: In a hospital or clinic environment, Operating room.



NOTE: The scale reading in drawing is in millimeters (mm)

Figure 5.2: ALLURE™ Surgical Mask- ENGINEERING DRAWING

5.6 Indications for Use [21 CFR 807.92(a) (5)]

ALLURE™ surgical 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.

5.7 Comparison of the technological characteristics with the predicate device [21 CFR 807.92(a) (6)]

The comparison chart below provides evidence to facilitate the substantial equivalence determination between ALLURE™ Surgical Mask and the predicate device (K133070) with respect to the intended use, technological characteristics and principles of operation.

Table 5.1. Comparison of Characteristics

Comparison parameters	**ALLURE™ Surgical Mask by Allure Gift Wraps Pvt Ltd**	**Surgical Face Mask, Ear Loops (Model 101B, 101G, 136B, 136G, 137B, 137G) and Surgical Face Mask, Tie-on (Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G)**	**Comparison**
510(k) Number	K212926	K133070	Different
Manufacturer	Allure Gift Wraps Pvt Ltd	BH Medical Products Co., Ltd.	Different
Proprietary Name	ALLURE™ Surgical Mask	Surgical Face Mask, Ear Loops, (Model 101B, 101G, 136B, 136G, 137B, 137G) and Surgical Face Mask, Tie-on, (Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G)	Different
Indications for Use	ALLURE™ surgical 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.	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
ASTM Level	1	1, 2 and 3	Similar
Design Feature	Tie-on/Ear loop	Tie-on/ear loop	Same
Mask Style	5 flat pleated	3 flat pleated	Similar

Traditional 510(k) Premarket Submission.
ALLURE™ Surgical Mask

Comparison parameters	**ALLURE™ Surgical Mask by Allure Gift Wraps Pvt Ltd**	**Surgical Face Mask, Ear Loops (Model 101B, 101G, 136B, 136G, 137B, 137G) and Surgical Face Mask, Tie-on (Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G)**	**Comparison**
			Mask
Duration and type of contact	Direct contact, less than 24 hours, skin contact	Direct contact, less than 24 hours, skin contact	Same
Product Performance Specifications	**Meets:** ASTM F1862/F1862M-17 ASTM F2101-21 ASTM F2100-19 ASTM F2299-03 ISO 10993-5: 2009 ISO 10993-10: 2010 EN 14683: 2019 Meet 16 CFR Part 1610	Meet ASTM F1862-07 Meet ASTM F2101-07 Meet ASTM F2299-03 Meet MIL-M-36954C Meet 16 CFR Part 1610 ISO 10993-5: 2009 ISO 10993-10: 2010	Similar
16 CFR Part 1610 Flammability Class	Class 1	Class 1	Same
Single Use	Yes	Yes	Same
Disposable	Yes	Yes	Same
Non-Sterile	Yes	Yes	Same
Material of Construction	Valve less, consisting of 5 layers made up of breathable PP non-woven, hot air insulation cotton, two layers of melt blown fabrics, non-woven fabrics and plastic nose strips and Elastic cord.	These are pleated 3 ply single use, disposable masks. Inner layers and outer layers are made of spun-bond polypropylene. Middle layer is made of melt blown polypropylene filter. Ear loops are Knitted Elastic loops (not made with natural rubber latex). Tie-on is made of spun-bond polypropylene. The nose piece is a malleable aluminium wire.	Similar
Outer facing Layer	Breathable PP non-woven, hot air insulation cotton	Spun bond Polypropylene	Similar
Middle Layer	Meltblown Polypropylene	Meltblown Polypropylene	Similar

Comparison parameters	**ALLURE™ Surgical Mask by Allure Gift Wraps Pvt Ltd**	**Surgical Face Mask, Ear Loops (Model 101B, 101G, 136B, 136G, 137B, 137G) and Surgical Face Mask, Tie-on (Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G)**	**Comparison**
Inner facing layer	Skin friendly non-woven fabrics	Spunbond Polypropylene	Similar
Binding	Spunbond Polypropylene	Spunbond Polypropylene	Similar
Nosepiece	Aluminium wire	Twisted metal strip	Similar
Earloop	Polyester	Cotton stretchable elastic type cord	Similar
Offered as fog free	NA	NA	Same
Offered with Visor	NA	NA	Same
Colour	White	Blue, Green	Different.
Dimension (width)	105 ± 5 mm	3.5” +/-0.25” 4.2” +/-0.25”	Different.
Dimension (length)	155 ± 5 mm	6.8” +/-0.25”	Different.
Over the counter use	Yes	Yes	Same
Biocompatibility	Non-cytotoxic, non-sensitizer, non-irritant	Non-cytotoxic, non-sensitizer, non-irritant	Same

The ALLURE™ Surgical Mask has similar indications for use statement as the predicate device and both devices have essentially the same intended use. The device also has similar technological characteristics as the predicate device. Both devices have similar material of construction and the same Product Performance Specifications.

5.8 Performance Data [21 CFR 807.92(b)]: Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b) (1)]

To verify that the ALLURE™ Surgical Mask meet the design requirements, testing was conducted in accordance with Surgical Masks - Premarket Notification [510(k)] Submission guidance, ASTM and ISO standards. Risk analysis was carried out in accordance with established inhouse acceptance criteria based on ISO 14971:2012.
The results of the performance testing using three non-consecutive lots demonstrate fulfilment of requirements as per device specific guidance_ Surgical Masks - Premarket Notification [510(k)] Submission as well as substantial equivalence with predicate.

Table 5.2. Non-Clinical Performance Tests

Testing/Standards	Purpose of the Test	Acceptance Criteria	Result
ASTM F1862/F1862M-17 Resistance of Medical Face Mask to Penetration by Synthetic blood	To determine the splash resistance/Fluid Penetration-Resistance to blood	Allure Surgical mask should be resistant to Penetration by Synthetic blood	Pass. Allure face mask is resistant to Penetration by Synthetic blood
ASTM F2101-19 EN 14683: 2014 Bacterial Filtration Efficiency	To determine the filtration efficiency of Allure Surgical mask by comparing the bacterial control counts upstream of the Allure Surgical Mask to the bacterial counts downstream	Bacterial Filtration Efficiency should be >95.0%	Pass. Filtration Efficiency was found to be >95.0%
ASTM F2101-19 EN 14683: 2014 Determination of Breathability	To determine the Breathability test (Differential Pressure Pa.	Level 1<5mmH_2O/cm^2 Level 2<6mmH_2O/cm^2 Level 3<6mmH_2O/cm^2	Pass. Allure Face mask meets the requirement for Level 1.

16 CFR Part 1610 Flammability	To determine the flammability as per 16 CFR Part 1610	Allure Surgical mask shall meet the as per requirements of Class 1 Normal flammability	Pass. Allure face mask is found to be of Class 1: Normal flammability
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	To evaluate the non-viable particle filtration efficiency (PFE) of the Allure Surgical Mask.	Particle Filtration Efficiency Test at 0.1 micron (%) should be >95%	Pass. Allure face mask meets the requirement for Level 1 >95

Table 5.3. Biocompatibility Performance tests

Category	Testing/Standards	Result
Test for in vitro cytotoxicity: Elution method.	ISO 10993-5:2009(E)	Based upon the results obtained in this study and in line with ISO 10993-5:2009(E), it is concluded that the given test item, ALLURE™ Surgical Mask, supplied by Allure Gift Wraps Pvt Ltd, is non-cytotoxic to Balb/c 3T3 cells.
Skin Sensitization Test in Guinea Pigs. (Guinea Pig Maximization Test)	ISO 10993-10:2010(E)	Based upon the results obtained in this study and in line with ISO 10993-10:2010(E), the given test item, ALLURE™ Surgical Mask, supplied by Allure Gift Wraps Pvt Ltd, is considered as non-sensitizer to Guinea Pigs.
Skin Irritation Test in New Zealand White Rabbits.	ISO 10993-10:2010(E)	Based upon the results obtained in this study and in line with ISO 10993-10:2010(E), the given test item, ALLURE™ Surgical Mask, supplied Allure Gift Wraps Pvt Ltd, is considered as non-irritant to New Zealand White Rabbits.

Traditional 510(k) Premarket Submission.
ALLURE™ Surgical Mask

5.9 Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b) (2)]

There was no clinical testing required for this device.

5.10 Statement of Substantial Equivalence [21 CFR 807.92(b) (3)]

Conclusion

The conclusion drawn from the non-clinical performance tests demonstrates that the ALLURE™ Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device.