December 7, 2021

Baylab USA, LLC
% Vardhini Kirthivas
Vice President - Regulatory Services
Freyr Solutions
Level 4, Building No. H-08, Phoenix SEZ, Phase 2, Gachibowli
Hyderabad, Telangana 500081
India

Re: K212302
Trade/Device Name: BAYLAB 3-Ply Surgical Mask (BEACON I)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 9, 2021
Received: November 10, 2021

Dear Vardhini Kirthivas:

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)*
K212302

Device Name
BAYLAB 3-Ply Surgical Masks (BEACON I)

Indications for Use *(Describe)*
BAYLAB 3-Ply Surgical Masks (BEACON I) 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 provided nonsterile.

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 K212302

1. Submitter Information:

Application Correspondent (US Agent):	Vardhini Kirthivas Freyr Global Regulatory Solutions and Services Level 4, Building No. H-08, Phoenix SEZ, Phase 2, Gachibowli, Hyderabad, Telangana, India, 500081
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Legal Manufacturer:	BAYLAB USA LLC
Phone:	214-907-2527
Contact Person:	Ashley Park
E-mail:	Ashley.park@baylabusa.com
Fax Number (including area code):	469-372-0414
Date Prepared:	22-June-2021

2. Device Identification:

Device Trade Name:	BAYLAB 3-Ply Surgical Masks (BEACON I)
Device:	Mask, Surgical
Regulation Description:	Surgical Apparel
Regulation Medical Specialty:	General & Plastic Surgery
Review Panel:	General Hospital
Device Class:	II
Regulation Number:	878.4040
Product Code:	FXX

3. Predicate Devices:

Table 1 – List of Predicate Devices

Device Name	510(k) Number
DemeMASK	K201479

4. Device Description

BAYLAB 3-Ply Surgical Masks (BEACON I) are nonwoven, pleated, 3-ply, single use, disposable flat surgical masks, manufactured in Bay Blue color. The surgical masks are to be secured on users by means of elastic ear loops.

5. Intended Use & Indications for Use

BAYLAB 3-Ply Surgical Masks (BEACON I) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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 provided nonsterile.

6. Comparison of Technological Characteristics

Table 2 – Comparison Table

S.No	Parameters		Predicate Device	Subject device	Comments
1.	Name		DemeMASK	BAYLAB 3-Ply Surgical Masks (BEACON I)	N/A
2.	510(k) Number		K201479	K212302	N/A
3.	Manufacturer		DemeTECH Corporation	BAYLAB USA LLC	N/A
4.	Product Code		FXX	FXX	Same
5.	Regulation Number		878.4040	878.4040	Same
6.	Intended Use/Indications of Use		The Disposable 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 provided nonsterile.	BAYLAB 3-Ply Surgical Masks (BEACON I) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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 provided nonsterile.	Same
7.	Material of Construction	Inner Layer	Spun-bond Polypropylene	Spunbond polypropylene	Same
		Outer Layer	Spun-bond Polypropylene	Spunbond polypropylene	Same
		Middle Layer	Meltblown polypropylene filter	Meltblown polypropylene filter	Same
		Ear loops	Spandex and Nylon- Not made with natural rubber latex	Spandex, Nylon, Polyester - Not made with natural rubber latex	Different, Note 1
		Nose Piece	Galvanized wire coated with polyethylene	Plastic (polyethylene) clad aluminum	Different, Note 2
8.	Dimensions		Length: 17.5 cm±1 cm Width: 9.5 cm±1 cm	Mask size: 7” x 3 ¾” (17.78 cm x 9.525 cm)	Same
9.	Color		Blue	Blue	Same
10.	Mask Style		Flat – pleated	Flat pleated, 3-ply	Same
11.	Design Features		Ear loop	Ear loop	Same
12.	Sterility		Non – Sterile	Non- Sterile	Same
13.	Use		Single Use	Single Use	Same

S.No	Parameters		Predicate Device	Subject device	Comments
14.	Latex		Not made with Natural Rubber Latex	Not made with Natural Rubber Latex	Same
15.	ASTM F2100 Level		Level 3	Level 3	Same
16.	Bacterial filtration efficiency		Pass at ≥ 99% **(ASTM F2101)**	Pass at >98% **(ASTM F2101)**	Different, Note 3
17.	Differential pressure (Delta-P)		Average 3.6 mmH_2O/cm^2 **(MIL-M-36954C)**	ΔP <6mm H_2O/cm^2 **(EN 14683)**	Different, Note 4
18.	Sub-micron particulate filtration efficiency		Pass at ≥99% **(ASTM F2299)**	Pass at >99% **(ASTM F2299)**	Similar, Note 5
19.	Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result		Pass at 160 mm Hg **(ASTM F1862)**	Pass at 160 mm Hg **(ASTM F1862)**	Same
20.	Flammability		**Class 1** (16 CFR Part 1610)	**Class 1** (16 CFR Part 1610)	Same
21.	Biocompatibility	Cytotoxicity, ISO 10993 5:2009	Pass ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic.	Pass ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic.	Same
		Irritation, ISO 10993-10:2010	Pass ISO 10993-10:2010/ under the conditions of the study, the subject device was non-irritating.	Pass ISO 10993-10:2010/ under the conditions of the study, the subject device was non-irritating.	Same
		Sensitization, ISO 10993-10:2010	Pass ISO 10993-10:2010/ under the conditions of study, the subject device was non-sensitizing.	Pass ISO 10993-10:2010/ under the conditions of study, the subject device was non-sensitizing.	Same

Note 1 & Note 2: The differences in the materials do not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials.

Note 3: The performance requirement for BFE as per ASTM F2100 is ≥98%. The performance of the subject device meets the requirements of ASTM F2100 version 2020 which is the revised version of FDA recognized consensus standard [Rec# 6-425] ASTM F2100-19. The subject device meets the criteria.

Note 4: We understand that MIL-M-36954C is the FDA recommended standard for differential pressure. However, the conformance to FDA Recognized consensus standard [Rec# 6-425], ASTM F2100-19 requires that Differential pressure be performed as per EN 14683:2019, Annex C.

We also understand that as per ASTM F2100-19, passing criteria for an ASTM level 3 mask with respect to differential pressure is <6.0mm H_20/cm^2 when tested in accordance with EN 14683:2019, Annex C. The subject device meets the criteria.

Note 5: The performance requirement for PFE as per ASTM F2100 is ≥98% when tested in accordance with ASTM F2299. The performance of the subject device meets the requirements of ASTM F2100 version 2020 which is the revised version of FDA recognized consensus standard [Rec# 6-425] ASTM F2100-19. The subject device meets the criteria.

7. Non-Clinical Testing

The following performance tests, in accordance with ASTM F2100 were conducted for the subject device:

- ASTM F1862 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 Part 1610 Standard for The Flammability of Clothing Textiles
- EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods Annex C - Method for determination of breathability (differential pressure)
- ASTM F2299- Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of surgical masks using a Biological Aerosol of Staphylococcus aureus.

Table 3 – Performance Testing - summary

Sr. No.	Test Method/ Standard	Purpose	Acceptance criteria	Results
1.	ASTM F 2101	Bacterial filtration efficiency	Level 3: ≥98%	Pass at >98%
2.	EN 14683	Differential Pressure (Delta-P)	Level 3: ΔP <6mm H_2O/cm_2	ΔP <6mm H_2O/cm_2
3.	ASTM F2299	Sub-micron particulate filtration efficiency	Level 3: ≥98%	Pass at >99%
4.	ASTM F1862	Resistance to penetration by synthetic blood	Level 3: 160mm Hg	Pass at 160mm Hg
5.	16 CFR Part 1610	Flammability	Class I	Class I

FDA's guidance, "Surgical Masks - Premarket Notification [510(k)] Submissions ", recommends evaluating the biocompatibility as described in the standard ISO10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” for limited contact devices, contacting intact skin.

The following Biocompatibility End points have been identified and tested in accordance appropriate biocompatibility standards.

- Cytotoxicity (ISO 10993-5)
- Irritation or intracutaneous reactivity (ISO 10993-10)
- Sensitization (ISO 10993-10)

Table 4 – Biocompatibility Testing - summary

Biological endpoint	Test Method	Purpose	Acceptance criteria	Test Result
Cytotoxicity	ISO 10993-5	Verify Cytotoxicity potential of the subject device	Non-cytotoxic	Pass - ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic.
Irritation and Sensitization	ISO 10993-10	Verify irritation and sensitization	Non-irritating and non-sensitizing	Pass ISO 10993-10:2010/ under the conditions of the study, the subject

		potential of the subject device		device was non-irritating and non-sensitizing.

8. 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, DemeMASK cleared under K201479.