September 22, 2021

Banyan USA LLC
% Timothy Kania
Consultant
MDI Consultants Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K211097
Trade/Device Name: Banyan USA Surgical Mask Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 13, 2021
Received: August 17, 2021

Dear Timothy Kania:

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)*
K211097

Device Name
Banyan USA Surgical Mask Level 3

Indications for Use *(Describe)*
The Banyan USA Surgical Mask Level 3 is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganism, body fluids, and particulate materials. This face mask are intended for use in infection control practices to reduce potential exposure to blood and body fluids. the face mask is single use, disposable device, 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

The assigned 510(k) number is: K211097

1. Submitter's Identification:

Manufacturer: Banyan USA, LLC
Address: 390 Oser Avenue
Hauppauge, NY 11788

Contact: Mr. Ricardo Ryan
Title: VP of Operations
Phone Number: 631-456-5447
Email: rryan@banyanppe.com

Date Summary Prepared: March 31, 2021

Official Correspondent: Mr. Tim Kania
mdi Consultants, Inc.
Phone Number: (732)-796-4565
Email: tim@mdiconsultants.com

2. Name of the Device:

Device Name(s): Banyan USA Surgical Mask Level 3
Model Number: M3WH

Common Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX

3. Information for the 510(k) Cleared Device (Predicate Device):

Predicate Device:
3-ply EcoGuard B with Earloop
K202096
EcoGuard Inc.

4. Device Description:

The Banyan USA Surgical Mask is composed of three-layers which are flat-pleated and ultrasonically welded together at the edges of the mask at embossment points. The mask materials consist of an outer layer (polypropylene spunbond, white), filter layer (polypropylene melt-blown, white) and inner layer web (polypropylene thermal-bonded, white (22 GSM Thermal Bond White Material)). Each mask has two ear loops ultrasonically welded onto the sides to secure the mask over the users' nose and mouth. The construction also includes a polyethylene wire nosepiece to provide a firm fit over the nose. The mask is a single use, disposable device, provided non-sterile.

5. Indications for Use:

The Banyan USA Surgical Mask Level 3 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table 2: Comparison to Predicate Device

Item	**Proposed Device:**	**Predicate Device:**	**Comparison**
510(k) Number	K211097	K202096	-
Manufacturer	Banyan USA, LLC	EcoGuard Inc.	-
Product Name	Banyan USA Surgical Mask Level 3	3-ply EcoGuard B with Earloop	Different
Model Number	M3WH	ECO01	Different
Classification	Class II Device Product Code: FXX Regulation Number: 21 CFR 848.4040	Class II Device Product Code: FXX Regulation Number: 21 CFR 848.4040	Same
Intended Use/Indications for Use	The Banyan USA Surgical Mask Level 3 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. These surgical masks are single use and disposable. Provided non-sterile.	The following EcoGuard 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 surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. These surgical masks are single use, disposable devices provided non-sterile.	Same
Material			
Outer Facing Layer	Spunbond polypropylene	Spunbond polypropylene	Similar
Middle Layer	Melt blown polypropylene	Melt blown polypropylene	Similar
Inner Facing Layer	Thermal bonded polypropylene (22 GSM Thermal Bond White Material)	Spunbond polypropylene	Different
Nose Piece	Polyethylene Nose Wire	Malleable Polyethylene Wire	Different

Ear Loops	White Knitted Nylon Elastic	Polyester Nylon/Spandex	Different
Mask Style	Flat Pleated	Flat Pleated	Similar
Color	White Colorant: None CAS#: None	Blue Colorant: Pigment Blue 15:3 CAS#: 147-18-8	Different
Design Features			
Specification and Dimensions	6.9 ± ¼" 3.7 ± ¼"	17.5cm ± 2.0cm (~6.9 ± 0.4") 9.5cm ± 2.0cm (~3.7 ± 0.4")	Similar
OTC Use	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level	Level 3	Level 3	Same
Non-Clinical Testing	ASTM F1862 ASTM F2299 ASTM F2101 EN 14683 16 CFR 1610	ASTM F1862 ASTM F2299 ASTM F2101 MIL-M-36954C 16 CFR 1610	Same
Biocompatibility Testing	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Same

7. Summary of Non-Clinical Tests:

The Banyan USA Surgical Mask Level 3 has been tested in accordance with the ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks. See Table 3 below for a summary of the non-clinical test results.

Table 3: Summary of Non-Clinical Testing

Test	**Purpose**	**Acceptance Criteria per ASTM F2100-11 Level 3 (AQL = 4.0%)**	**Proposed Device Test Result: Banyan USA Surgical Mask**	
			ASTM F2100-11 Level 3	**Average**
Fluid Resistance Performance (ASTM F1862)	Determine synthetic blood penetration resistance	160 mmHg	Pass at 160 mmHg (96/96) 32 Samples from 3 non-consecutive lots	N/A
Particulate Filtration Efficiency (ASTM F2299)	Determine bacterial filtration efficiency	≥ 98%	Pass (96/96) 32 Samples each from 3 non-consecutive lots	98.69%

Bacterial Filtration Efficiency (ASTM F2101)	Determine submicron particulate filtration efficiency	≥ 98 %	Pass (96/96) 32 Samples each from 3 non-consecutive lots	99.22%
Differential Pressure (Delta P) EN 14683:2019	Determine breathing resistance or differential pressure	< 6.0 mmH_2O / cm^2	Pass (96/96) 32 Samples each from 3 non-consecutive lots	3.82 mm H_20/cm^2
Flammability CFR 16 1610	Determine flammability	Class 1	Class 1 Pass (96/96) 32 Samples each from 3 non-consecutive lots	N/A

Table 4: Summary of Biocompatibility Testing

Biocompatibility **ISO 10993-I Evaluation and testing within a risk management process**		
Test	**Test Findings**	**Result**
Cytotoxicity ISO 10993-5 Tests for in vitro cytotoxicity of medical devices	Under the conditions of the study, the device is non-cytotoxic	Banyan USA Surgical Mask Level 3 :Pass
Irritation ISO 10993-10 Tests for irritation	Under the conditions of the study, the device is non-irritating	Banyan USA Surgical Mask Level 3: Pass
Sensitization ISO 10993-10 Tests for skin sensitization	Under the conditions of the study, the device is non-sensitizing	Banyan USA Surgical Mask Level 3:Pass

8. Summary of Clinical Test:
NA

9. Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the proposed device, the Banyan USA Surgical Mask Level 3, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K202096.