December 8, 2021

MAF Clothing Pvt Ltd Unit-3
Thomas Knott
Senior Regulatory Advisor
Benjamin L. England and Associates, LLC
810 Landmark Dr, Suite 126
Glen Burnie, Maryland 21061

Re: K211487
Trade/Device Name: MAF Guard (Ear Loop model SM3P-MB25-2511; Tie-on model SM3P-MB25-2521)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 11, 2021
Received: November 15, 2021

Dear Thomas Knott:

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, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211487

Device Name
MAF Guard (Ear Loop model SM3P-MB25-2511; Tie-on model SM3P-MB25-2521)

Indications for Use *(Describe)*
MAF Guard is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluid 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.

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

Date of Summary Prepared: November 30, 2021
510(k) Number: K211487

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On Behalf of:	MAF CLOTHING PVT LTD UNIT-3
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Contact:	Mr. Kirit Jagani (Business Head)

1. Regulatory Information

Proprietary Name:	MAF Guard (Ear Loop model SM3P-MB25-2511; Tie-on model SM3P-MB25-2521)
Classification Name:	Surgical Face Mask, Apparel
Classification:	Class II
Product Code:	FXX
Panel	General Surgery Devices
Regulation:	21 CFR 878.4040

2. Predicate Device

510(k) Number:	K173062
Device Name:	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))
Recalls:	A search of the recall database revealed no design-related recalls.

3. Device Description

The surgical face mask is a non-sterile, single use, three-layer, flat, pleated style with ear loops or tie-on strings and a nose piece. The mask is 175 ± 5 mm by 95 ± 3 mm. The outer, blue layer and the inner, white layer are spunbond polypropylene, and the middle layer consists of melt-blown polypropylene filter. One model of the mask is secured to the face with two ear loops made of polyester Spandex that are 150 ± 10 mm long. The other model is secured with four spin bond polypropylene tie-on strings that are 450 ± 10 mm long. A nosepiece of steel core wire coated with polyethylene resin that is 110 ± 5 mm long conforms the mask to the shape of the nose.

4. Indications for Use

MAF Guard is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluid 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.

5. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

CLASSIFICATION INFORMATION			
510(k) Number	K211487	K173062	N/A
Manufacturer	MAF Clothing Pvt. Ltd.	V&Q Manufacturing Corporation	N/A
Proprietary Name	MAF Guard (Models Ear Loop – SM3P-MB25-2511, Tie-on – SM3P-MB25-2521.	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))	N/A
Common Name	Surgical Face Mask	Surgical Face Mask	Same
Product Code	FXX	FXX	Same
Classification	Class II	Class II	Same
Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for Use	MAF Guard is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluid 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.	Non Woven Face Mask (Models: VQN0185W (ear loop) and VQN0185B (ties)) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Similar
Model	Three ply, flat pleated with ear loops and ties	3 Ply, Flat-Pleated Style with ear loops and ties	Same

MATERIALS			
Outer Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Steel core wire coated with Polyethylene resin	White aluminum strip covered by PP covering	Different
Ear Loops	Polyester Spandex	Urethane elastic fiber	Different
Tie strips:	Spunbond polypropylene	Spunbond polypropylene	Same
Color	Blue outer layer	Blue	Same
Width	95 ± 3 mm	95 mm	Same
Length	175 ± 5 mm	175 mm	Same
OTC Use?	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single Use?	Yes	Yes	Same
ASTM F2100	Level 3	Level 2	Different
ASTM F1862 Fluid Resistance Performance	32 out of 32 pass at 160 mm Hg for each of three lots	Pass at 120 mm Hg	Different
ASTM F2299 Particulate Filtration Efficiency	Mean for three lots = 99.88%, 99.89%, and 98.50%, respectively	Average 99.74% at 0.1µm	Similar
ASTM F2101 Bacterial Filtration Efficiency	Mean for three lots = 98.9%, 98.5%, and 98.4%	Average 99.4%	Similar
Differential Pressure (Delta P)	Mean for three lots = 2.11, 2.57, and 4.60 mm H_2O/cm^2	Average 2.7 mm H_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility Testing	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same

Differences in technological characteristics do not raise different questions of safety and effectiveness.

6. Non-clinical Tests Performed on the Proposed Device

The proposed device was tested 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 5, 2004.

Table 2 - Performance Testing

Test Method	Purpose	Acceptance Criteria	Result
ASTM 2100			Meets requirements for Level 3
Fluid Resistance Performance ASTM F1862	To evaluate the resistance to penetration by synthetic blood, minimum pressure in mm Hg	Level 3 requirement: 29 out of 32 passed at 160 mm Hg	Pass 32 out of 32 passed at 160 mm Hg for three non-consecutive lots
Particulate Filtration Efficiency ASTM F2299	To evaluate the Sub-micron particulate filtration efficiency at 0.1 micron (%)	Level 3 requirement: ≥ 98%	Pass Mean for three non-consecutive lots = 99.88%, 99.89%, and 98.50%
Bacterial Filtration Efficiency ASTM F2101	To evaluate the BFE of the test article using a biological aerosol of Staphylococcus aureus (%)	Level 3 requirement: ≥ 98%	Pass Mean for three non-consecutive lots = 98.9%, 98.5%, and 98.4%
Differential Pressure (Delta P) EN 14683	To evaluate the Different pressure (mm H_2O/cm^2)	Level 3 requirement: < 6 mm H_20/cm^2	Pass Mean for three non-consecutive lots = 2.11, 2.57, and 4.60 mm H_2O/cm^2
Flammability 16 CFR 1610	To evaluate the flammability	Class 1	Pass 3 non-consecutive lots of each mask model

Table 3 - Biocompatibility Testing

Item	Proposed Device	Acceptance Criteria	Result
ISO 10993-5	Non-Cytotoxic	Non-Cytotoxic	Pass
ISO 10993-10	Non-Sensitizing	Non- Sensitizing	Pass
ISO 10993-10	Non-Irritating	Non-Irritating	Pass

7. Conclusion

There is no clinical study included in this submission. The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

****END OF 510(k) SUMMARY*****