December 15, 2022

PM Excellence LLC
Nina Bektic-Marrero
Managing Director
2864 Wilson Avenue
Bellmore, New York 11710

Re: K220520
Trade/Device Name: PM Excellence SEQUR 100 Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 12, 2022
Received: December 13, 2022

Dear Nina Bektic-Marrero:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220520

Device Name
PM Excellence SEQUR 100 Surgical Face Mask

Indications for Use *(Describe)*
The PM Excellence SEQUR 100 Surgical Face Masks (for single use only) are indicated as protective nose and mouth covering for healthcare workers and patients. These face masks are intended for use in infection control practices as well as any medical or surgical procedure or situations where there is a risk of exposure to microorganism, body fluid, and particulate materials.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510[k] Summary

This Summary of 510(k) pre-market notification was prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: May 28,2022

1. Submitter Identification:

Name: PM Excellence, LLC
Address: 2864 Wilson Avenue, Bellmore, NY 11710
Official Correspondent: Nina Bektic-Marrero
Title: Managing Director
E-mail: nina@mypmexcellence.com
Telephone: +1(917) 640-7980

2. Regulatory Information:

Name of Device: Surgical Mask (single use only)
Proprietary Name: PM Excellence SEQUR 100 Surgical Face Mask
Panel: General Hospital
Regulatory Class: Class II
Classification Regulation Name: 21CFR 878.4040, Surgical Apparel
Product Code: FXX
Classification Name: Mask, Surgical
Submission type: Traditional 510(k)

3. Primary Predicate Device Information:

Primary Predicate Device
Manufacturer: Wellmien (Suzhou) Import and Export Trading Co., Ltd.
Device: Surgical Face Mask
510(k) No.: K101000

4. Device Description:

PM Excellence SEQUR 100 Surgical Face Mask (light blue) for single use only, are pleated 3-ply masks that consist of the following materials: hydrophobic nonwoven PP (polypropylene) spunbond 35 gsm, 17.5cm, light blue (outer layer); nonwoven PP (poly propylene) spunbond 30gsm, 19.5cm, white (inner layer); and nonwoven PP (polypropylene) meltblown 30gsm, 17.5cm, white (middle filter layer). The PM Excellence SEQUR 100 Surgical Face Mask Light Blue also utilizes soft, latex-free elastic earloops and malleable wire nose piece. All the materials

used in the construction of the PM Excellence SEQUR 100 Surgical Face Mask (light blue) are substantially equivalent to those used in currently marketed devices, including the primary predicate device K101000

5. Intended Use

The PM Excellence SEQUR 100 Surgical Face Masks (for single use only) are indicated as protective nose and mouth covering for healthcare workers and patients. These face masks are intended for use in infection control practices as well as any medical or surgical procedure or situations where there is a risk of exposure to microorganism, body fluid, and particulate materials.

6. **Comparison to Primary Predicate Device:**

PM Excellence SEQUR 100 Surgical Face Mask Light Blue for single use only, is compared with its primary predicate device: K101000, Surgical Face Mask by Wellmien (Suzhou) Import and Export Trading Co., Ltd. The design, dimensions, material, and performance of both devices are very similar, and the two products are substantially equivalent in safety and effectiveness.

The only difference between the primary predicate device and the subject device is that the three layers of Polypropylene materials have very similar but not the same gsm (grams per square meter). It is important however to note that this difference does not raise any concerns regarding the safety and effectiveness of the subject device as evidenced by the test results for biocompatibility and performance.

i. Comparison to the Primary Predicate Device

Description	**Subject Device K220520 (PM Excellence SEQUR 100 Surgical Face Mask)**	**Primary Predicate Device K101000 Wellmien Surgical Mask**
Applicant	PM Excellence, LLC	Wellmien (Suzhou) Import and Export Trading Co., Ltd
Classification Regulation	21CFR 878.4040	21CRF 878.4040
Classification, Product Code	Class II, FXX	Class II, FXX
Common name	Surgical Face Mask	Surgical Face Mask

Indication for use	The PM Excellence SEQUR 100 Surgical Face Masks (for single use only) are indicated as protective nose and mouth covering for healthcare workers and patients. These face masks are intended for use in infection control practices as well as any medical or surgical procedure or situations where there is a risk of exposure to microorganism, body fluid, and particulate Materials.	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.
Model	Earloops, Flat Pleated, 3 layers	Earloops, Flat Pleated, 3 layers
Material	Outer layer: Nonwoven Spunbond hydrophobic Polypropylene Light Blue **35 gsm ± 2 gsm** Middle layer: Nonwoven Melt-blown polypropylene filter white **30 gsm ± 2 gsm** Inner layer: Nonwoven Spunbond Polypropylene white **30 gsm ± 2 gsm** Nose wire: Polyethylene coated steel wire Earloops: Polyester Elastic Non-Latex	Outer facing layer: Spunbond Polypropylene Light Blue **33 gsm ± 2 gsm** Middle layer: Melt-blown polypropylene filter white **33 gsm ± 2 gsm** Inner facing layer: Spunbond Polypropylene white **25 gsm ± 2 gsm** Nose wire: Polyethylene coated steel wire Ear loops: Polyester
Color	Light Blue	Blue
Dimension (Width)	17.5cm ± 0.2cm	17.5cm ± 0.2cm
Dimension (Length)	9.5 ± 0.2cm	9.5 ± 0.2cm
Earloop Length	16.0 cm ± 0.5 cm	16.0 cm ± 0.5 cm
Nose Wire Length	11.0 cm ± 0.5 cm	11.0 cm ± 0.5 cm
OTC use	Yes	Yes

Sterility	Non-sterile	Non-sterile
Usage	Single use, disposable	Single use, disposable

i. Comparison of Device Performance

Performance Testing	Subject Device (PM Excellence SEQUR 100 Surgical Face Mask)	Primary Predicate Device (K101000)
Fluid Resistance Performance	31 out of 32 pass at 160 mmHg	32 out of 32 pass at 160 mmHg
Particle Filtration Efficiency	From 98.98% to 99.06%	99.8%
Bacterial Filtration Efficiency	From 99.85% to 99.96%	99.9%
Differential Pressure (Delta P)	5.0 to 5.3 mmH_2O/cm^2	3.7-4.0 mmH_2O/cm^2
Flammability	Class I	Class I
Biocompatibility	The subject device is non-cytotoxic, non- sensitizing and non-irritating.	Biocompatible. Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.

ii. Discussion of non-clinical tests performed to determine substantial equivalence

The following non-clinical tests were performed to determine substantial equivalence. Tests were conducted following the recommended procedures outlined in the respective

consensus standards. Test results met all relevant requirements in the test standards and are comparable to the primary predicate device.

(1) Bacterial filtration efficiency (BFE): ASTM F2101
(2) Differential Pressure (Delta P) EN 14683:2019 Annex C
(3) Latex particle challenge (PFE): ASTM F2299-03
(4) Flammability: 16CFR 1610
(5) Biocompatibility: ISO10993
(6) Fluid Resistance – Synthetic Blood Penetration: Resistant Test: ASTM F1862

More detail comparison of the design, technical, and performance characteristics to the primary predicate device are summarized in Section 11: Executive Summary and Primary Predicate Comparison.

7. Discussion of Clinical Tests Performed

Not applicable

8. Conclusions

The PM Excellence SEQUR 100 Surgical Face Mask Light Blue for single use only have the same intended use, technological characteristics and performance effectiveness as the primary predicate device K101000. Furthermore, bench testing contained in this submission demonstrates that the technological characteristics do not raise any new questions of safety or effectiveness. PM Excellence SEQUR 100 Surgical Face Mask for single use only are substantially equivalent to the primary predicate device K101000.

i.Compliance with Recognized Standards

PM Excellence, LLC hereby certifies that testinghas beenconducted in accordance with and has met the acceptance criteria specified in the table below, prior to the product being marketed.

Test Method	Description	Acceptance Criteria
ASTM F1862	Resistance to Penetration by Synthetic Blood Level 3 160mmHg	29 out of 32 pass at 160 mmHg
EN 14683: 2019 Annex C	Differential Pressure	< 6.0mmH_2O/cm^2
ASTM F2299	Sub-Micron Particulate	≥ 98%
BFE	Bacterial Filtration Efficiency	≥ 98%
16 CFR Part 1610	Flammability	Class I
ISO 10993	Cytotoxicity	Pass
ISO 10993-10	Maximization Sensitization	Pass
ISO 10993-23	Intracutaneous Study	Pass

ii.Performance Data

The proposed devices were 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.

Item	**Proposed device**	**Acceptance criteria**	**Result**
Fluid Resistance Performance	31 out of 32 pass at 160 mmHg	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency	From 98.98% to 99.06%	≥ 98%	Pass
Bacterial Filtration Efficiency	From 99.85% to 99.96%	≥ 98%	Pass
Differential Pressure (Delta-P) Test	5.0 to 5.3 mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass
Flammability Testing	Class 1	Class 1	Pass

iii.Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective, and performs as well as or better than the legally marketed primary predicate device K101000, Surgical Face Mask