October 4, 2021

J.K. Private Stock Inc.
% Nickita Alexiades
Regulatory Affairs Consultant/Engineer
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K211425
Trade/Device Name: Private Stock Labs Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 26, 2021
Received: August 31, 2021

Dear Nickita Alexiades:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211425

Device Name
Private Stock Labs Surgical Face Mask

Indications for Use *(Describe)*
The Private Stock Labs Surgical Face Mask is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. Private Stock Labs Surgical Face Mask is 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

. 1. Submitter's Identification:

Applicant: J.K. PRIVATE STOCK INC.
Address: 68-05 Fresh Meadow Lane, Fresh Meadows, NY 11365, USA

Contact Person: Jonathan Koon
Tel: (718)-886-3163
Email: jonathan.koon@gmail.com

Date Summary Prepared: January 13, 2020

Official Correspondent: Mr. Nickita Alexiades
Mdi Consultants, Inc.
Address: 55 Northern Blvd. Suite 200, Great Neck, NY, United States
Tel: 201-220-2152
Email: nickita@mdiconsultants.com

2. Name of the Device:

Proprietary Name: Private Stock Labs Surgical Face Mask
Classification Name: Mask, Surgical
Common Name: Surgical Mask
Regulatory Class: II
Product Code: FXX
Regulation Name: Surgical Apparel
Regulation Number: 878.4040
Review Panel: General Hospital

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

Surgical Face Mask, K182515

Surgical Face Mask

Wuhan Dymex Healthcare Co., Ltd.

No reference devices were used in this submission.

4. Device Description:

PRIVATE STOCK LABS Surgical Face Mask is a single use, three-layer, flat-pleated mask with ear loops and a nose piece. The Surgical Face Mask is manufactured with three layers, of which the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear

loops are not made with latex materials, but are made of spandex. The nose piece in the layers of face mask allows the user to fit the face mask around their nose, which is made of malleable polyethylene wire. The surgical mask will be provided in green of outside and white of inside. PRIVATE STOCK LABS Surgical Face Mask is provided non-sterile and for single use.

5. Indications for Use:

The Private Stock Labs Surgical Face Mask is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. Private Stock Labs Surgical Face Mask is 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.

6. Technological Characteristics Comparison:

Table 1: Comparison to Predicate Device

Device	Proposed device	Predicate device	Comparison
510(k) Holder	J.K. PRIVATE STOCK INC.	WUHAN DYMEX HEALTHCARE CO., LTD	--
510(k) Number		K182515	--
Name	Private Stock Labs Surgical Face Mask	Surgical Face Mask	--
Model	PSL-SA3		--
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Intended use	The Private Stock Labs Surgical Face Mask is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. Private Stock Labs Surgical Face Mask is 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
Mask style	Flat Pleated	Flat Pleated	Same
Design	Ear loop	Ear loop	Same
Layers	Three	Three	Same
Color	Green outside; white inside	Yellow	Similar Note 1
Target population	Adults	Adults	Same
Dimension (Length)	175mm±5mm	17.5cm±0.2cm	Similar Note 2
Dimension (Width)	95mm±5mm	9.5cm±0.2cm	
Sterility	Non-sterile	Non-sterile	Same
Use	Single use, disposable	Single use, disposable	Same

Anatomical site	Nose and mouth	Nose and mouth	Same
Environment of use	OTC	OTC	Same
Material			
Outer facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
Inner facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Ear loops	Spandex	Spandex	Same
Nose piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
Colorants	Disperse Blue 359 - CAS No. 62570-50-7 Disperse Blue 360 - CAS No. 17095-24-8 Disperse Red 60 - CAS No. 17418-58-5 Disperse Yellow 54 – Cas No. 7576-65-0	Unknown	Similar Note 1
ASTM F2100 Level	Level 2	Level 2	Same
Biocompatibility (limited contact (<24h) surface devices on intact skin)			
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing.	Same
Differences between Subject device and Predicate Device:			

Note 1:

Biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

Note 2:

The tolerance of dimension are a little different between proposed device and predicate device.

7.Summary of Non-Clinical Tests :

The following testing was conducted to demonstrate that the subject device (3 non-consecutive lots with each lot containing 32 samples) met the acceptance criteria and specification of the standard shown below.

Test Methodology	Purpose	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	This test is performed to evaluate Personal Protective Equipment against fluid penetration. An arterial spray is simulated to test the PPE.	29 out of 32 pass at 120mmHg	Lot 1: 32 out of 32 pass at 120mmHg Lot 2: 32 out of 32 pass at 120mmHg Lot 3: 32 out of 32 pass at 120mmHg
Particulate Filtration Efficiency ASTM F2299	The PFE test is performed to evaluate the non-viable particle filtration efficiency of the test article.	≥ 98%	Lot 1: 99.9% 32 out of 32 pass Lot 2: 99.9% 32 out of 32 pass Lot 3: 99.9% 32 out of 32 pass
Bacterial Filtration Efficiency ASTM F2101	The BFE test is performed to determine the bacterial filtration efficiency of test articles.	≥ 98%	Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%
Differential Pressure (Delta-P) MIL-M-36954C	The purpose of this test is to ensure the drop in pressure is not too great so the user may breathe through the subject device.	< 6.0mmH2O/cm2	Lot 1: 5.75 mmH_2O/cm^2 Lot 2: .0 mmH_2O/cm^2 Lot 3: 3.94 mmH_2O/cm^2
Flammability class 16CFR 1610	The purpose of this test is to ensure the subject device does not ignite when exposed to flame.	Class 1	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1

8.Discussion of Clinical Tests Performed:

No clinical study is included in this submission.

9.Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Wuhan Dymex Healthcare Co., Ltd. Disposable Surgical Face Mask cleared under K182515.