August 19, 2021

Homtex, Inc.
Jeremy Wootten
President and CFO
2125 2nd Avenue SW
Cullman, Alabama 35055

Re: K211066
Trade/Device Name: Sovereign America Surgical Mask, Model Number: 2000SM2, Sovereign America Surgical Mask, Model Number: 2000SM3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 16, 2021
Received: July 19, 2021

Dear Jeremy Wootten:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211066

Device Name
Sovereign America Surgical Mask, Model: 2000SM2

Indications for Use *(Describe)*
Sovereign America Surgical Mask is intended for use by adult patients and healthcare personnel to protect against the transfer of microorganisms, bodily 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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K211066

Device Name
Sovereign America Surgical Mask, Model: 2000SM3

Indications for Use *(Describe)*
Sovereign America Surgical Mask is intended for use by adult patients and healthcare personnel to protect against the transfer of microorganisms, bodily 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 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.

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510(K) SUMMARY
K211066

This 510(K) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Preparation Date:

August 10, 2021

2. Submitter:

Homtex, Inc.
2125 2nd Avenue SW
Cullman AL 35055
Phone: 256-734-3937
Fax: 256-734-2043

Contact: Jeremy Wooten, President and CFO
Email: jeremy.wootten@homtex.com

3. Proposed Devices:

510(k) Number:	K211066
Trade Name:	Sovereign America Surgical Mask, Model 2000SM2 Sovereign America Surgical Mask, Model 2000SM3
Common Name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Classification:	Class II
Product Code:	FXX

4. Predicate Devices:

510(k) Number:	K160269
Trade Name:	San-M Package Co., Ltd. Level 2 and 3 Surgical Face Mask (Ear loops and Tie-on)
Common Name:	Surgical Mask

Regulation Number: 21 CFR 878.4040
Regulatory Class: Class II
Product Code: FXX

5. Device Description:

The Sovereign America Surgical Mask, Models 2000SM2 and 2000SM3, is a single use, three-layer, flat-pleated surgical mask with ear loops and a nose piece. Each device is composed of three layers of nonwoven polypropylene, with the outer layer (Layer 1) and inner layer (Layer 3) being spun-bond nonwoven polypropylene, and the middle layer (Layer 2) being melt-blown nonwoven polypropylene. Layer 1 contains a blue pigment. Each device utilizes two elastic ear loops, ultrasonically welded to the mask, to hold the device in place over the users' mouth and nose. The ear loops are polyester spandex elastic, and not made with natural rubber latex. Each device also utilizes a malleable nose piece, made of polypropylene coated aluminum wire, to allow the user to fit the device around the bridge of the nose. Each is provided non-sterile and intended to be a single use, disposable device.

6. Intended Use:

Each Sovereign America Surgical Mask is intended for use by adult patients and healthcare personnel to protect against the transfer of microorganisms, bodily 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. Each proposed device is a single use, disposable device, provided non-sterile.

7. Comparison to Predicate Devices:

Table 1: Summary of Technological Characteristics with the Predicate Device

Feature	Proposed Devices		Predicate Devices		Comparison
	Level 2	Level 3	Level 2	Level 3	
Manufacturer	Homtex, Inc.		San-M Package Co., Ltd.		-
510(k) number	K211066		K160269		-
Device Common Name	Surgical Mask		Surgical Mask		Same
Classification	Class II Device, FXX (21 CFR878.4040)		Class II Device, FXX (21 CFR878.4040)		Same

Intend use		The Sovereign American Surgical Mask is intended for use by adult patients and healthcare personnel to protect against the transfer of microorganisms, bodily 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 non-sterile.	The surgical face masks are intended to be worn toprotect 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 non-sterile.		Similar
Model Style		Flat-pleated; ear loops	Flat-pleated; ear loops		Same
Material	**Outer layer**	Spunbond nonwoven polypropylene	Polypropylene		Similar
	Middle layer	Melt-blown nonwoven polypropylene	Two layers - Spunbond polypropylene and Meltblown polypropylene		Similar
	Inner layer	Spunbond nonwoven polypropylene	Polypropylene		Similar
	Nose Piece	Polypropylene coated aluminum wire	Polyethylene coated steel wire		Similar
	Ear loop	Polyester spandex elastic	Polyester, polyurethane with polyester spunbond side tapes		Different
Color		Blue	White or blue		Similar
Dimension (Width)		175 mm	175 ± 5 mm	180 ± 5 mm	Similar
Dimension (Length)		95 mm	90 ± 3 mm	90 ± 3 mm	Similar
OTC use		Yes	Yes		Same
Sterility		Non-Sterile	Non-Sterile		Same
Use		Single Use, Disposable	Single Use, Disposable		Same
Latex		Not Made with Natural Rubber Latex	Unknown		Unknown
Performance (ASTM F2100)					
ASTM F2100 Level		Level 2	Level 3	Level 2	Level 3	Same
Fluid Resistance (ASTM F1862)		32/32 passed at 120 mm Hg	31/32 passed at 160 mm Hg	Passed at 120 mm Hg	Passed at 160 mm Hg	Same
Bacterial Filtration Efficiency (ASTM F2101)		Passed at 99.1 - 99.9%	Passed at 99.1 - 99.9%	Passed at >98%	Passed at >99%	Simliar

Particulate Filtration Efficiency (ASTM F2299)	Passed at 99.55 - 99.91%	Passed at 99.55 - 99.91%	Passed at 99.6%	Passed at 99.7%	Similar
Differential Pressure (EN 14683/MIL-M-36954C)	Passed at 2.5 - 3.3 mm H_2O/cm^2	Passed at 2.5 - 3.3 mm H_2O/cm^2	Passed at 1.6 mm H_2O/cm^2	Passed at 2.5 mm H_2O/cm^2	Similar
Flammability (16 CFR 1610)	Passed as Class 1		Passed as Class 1		Same
Biocompatibility					
Cytotoxicity (MEM Elution) ISO 10993-5:2009	Non-Cytotoxic		Non-Cytotoxic		Same
Intracutaneous Reactivity ISO 10993-10:2010	Non-Irritating		Non-Irritating		Same
Kligman Maximization Sensitization ISO 10993-10:2010	Non-Sensitizing		Non-Sensitizing		Same

8. Non-Clinical Testing:

Sovereign America Surgical Mask, Models 2000SM2 and 2000SM3, has been tested in conformity with the recognized consensus standards outlined in the *Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions* issued on March 5, 2004 and in ASTM F2100-19 *Standard Specification for Performance of Materials Used in Medical Face Masks*, including performance tests for 1) fluid resistance; 2) bacterial filtration efficiency; 3) particulate filtration efficiency; 4) differential pressure; and 5) flammability as well as biocompatibility tests. The performance testing and biocompatibility testing results showed that Sovereign America Surgical Mask, Models 2000SM2 and 2000SM3, passed all acceptance criteria in the consensus standards as set forth in Tables 2, 3, and 4 below.

Table 2: Performance Testing - Sovereign America Surgical Mask Model 2000SM2

Testing Standards	Acceptance Criteria ASTM F2100 Level 2	Sovereign America Surgical Mask Model 2000SM2	Predicate Device (K160269)	Result
Fluid Resistance (ASTM F1862)	29/32 pass at 120 mm Hg	32/32 pass at 120 mm Hg	Pass at 120 mm Hg	Meets or exceeds acceptance criteria
Bacterial Filtration Efficiency (ASTM F2101)	≥ 98%	99.1 - 99.9%	≥ 98%	Meets or exceeds acceptance criteria

Particulate Filtration Efficiency (ASTM F2299)	≥ 98%	99.55 - 99.91 %	99.6%	Meets or exceeds acceptance criteria
Differential Pressure (EN 14683/ MIL-M-36954C)	< 6.0 mm H_2O/cm^2	2.5 - 3.3 mm H_2O/cm^2	2.5 mm H_2O/cm^2	Meets or exceeds acceptance criteria
Flammability (16 CFR 1610)	Class 1	Class 1	Class 1	Meets or exceeds acceptance criteria

Table 3: Performance Testing - Sovereign America Surgical Mask Model 2000SM3

Testing Standards	Acceptance Criteria ASTM F2100 Level 3	Sovereign America Surgical Mask Model 2000SM3	Predicate Device (K160269)	Result
Fluid Resistance (ASTM F1862)	29/32 pass at 160 mm Hg	31/32 pass at 160 mm Hg	Pass at 160 mm Hg	Meets or exceeds acceptance criteria
Bacterial Filtration Efficiency (ASTM F2101)	≥ 98%	99.1 - 99.9%	≥ 99%	Meets or exceeds acceptance criteria
Particulate Filtration Efficiency (ASTM F2299)	≥ 98%	99.55 - 99.91 %	99.7%	Meets or exceeds acceptance criteria
Differential Pressure (EN 14683/ MIL-M-36954C)	< 6.0 mm H_2O/cm^2	2.5 - 3.3 mm H_2O/cm^2	1.6 mm H_2O/cm^2	Meets or exceeds acceptance criteria
Flammability (16 CFR 1610)	Class 1	Class 1	Class 1	Meets or exceeds acceptance criteria

Table 4: Biocompatibility Testing – Sovereign America Surgical Mask Model 2000SM2 and 2000SM3

Testing Items	Standards	Results	Result
Cytotoxicity (MEM Elution)	ISO 10993-5:2009	Pass (Non-Cytotoxic)	Meets or exceeds acceptance criteria
Intracutaneous Reactivity	ISO 10993-10:2010	Pass (Non-Irritating)	Meets or exceeds acceptance criteria
Kligman Maximization Sensitization	ISO 10993-10:2010	Pass (Non-Sensitizing)	Meets or exceeds acceptance criteria

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and performs as well as or better than the legally marketed predicate device, K160269.