March 19, 2021

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

Re: K201095
Trade/Device Name: Sovereign America Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 11, 2021
Received: February 26, 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,

Ryan Ortega, Ph.D.
Acting 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)*
K201095

Device Name
Sovereign America Surgical Mask, Model: 2000SM1

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

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510(K) SUMMARY

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

1. Preparation Date:

March 17, 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 Device:

Trade Name:	Sovereign America Surgical Mask, Model 2000SM1
Common Name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Classification:	Class II
Product Code:	FXX

4. Predicate Device:

510(k) Number:	K153409
Trade Name:	Protect U Guard Earloop Mask 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 is a single use, three-layer, flat-pleated surgical mask with ear loops and a nose piece. The 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. The 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. The 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. The mask is provided non-sterile and intended to be a single use, disposable device.

6. Intended Use:

Sovereign America Surgical Mask is intended for use by healthcare personnel to protect both patients and healthcare personnel against the transfer of microorganisms, bodily fluids and particulate material. This is a single use, disposable device, provided non-sterile.

7. Comparison to Predicate Device:

Table 1: General Comparison

Item	Proposed Device	Predicate Device	Comparison
Manufacturer	Homtex, Inc.	Protect U Guard, LLC	
Product Code	FXX	FXX	Same
Classification and Regulation	Class II 21 CFR878.4040	Class II 21 CFR878.4040	Same
Intend use	The Sovereign American Surgical Mask is intended for use by healthcare personnel to protect both patients and healthcare personnel against the transfer of microorganisms, bodily fluids and particulate material. This is a single use, disposable device, provided non-sterile.	The Protect U Guard Earloop Mask and Tie-On Mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids and airborne particles. This device is single use and provided non-sterile.	Similar

Model Style		Flat-pleated earloops	Flat pleated Earloops or tie-on	Same
Material	**Outer layer**	Spunbond nonwoven polypropylene	Spunbound polypropylene	Same
	Middle layer	Melt-blown nonwoven polypropylene	Meltblown polypropylene	Same
	Inner layer	Spunbond nonwoven polypropylene	Spunbound polypropylene	Same
	Nose Piece	Polypropylene coated aluminum wire	Aluminum strip	Similar
	Ear loops	Polyester spandex elastic	Urethane elastic fiber	Similar
Color		Blue	Blue, White, or Green	Similar
Dimension (Width)		17.5 cm	17.7 cm	Similar
Dimension (Length)		9.5 cm	9.5 cm	Same
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	Not Made with Natural Rubber Latex	Same
Performance (ASTM F2100 Level 1)				
Fluid Resistance (ASTM F1862)		29 out of 32 passed at 80 mmHg	29 out of 32 passed at 80 mmHg	Same
Bacterial Filtration Efficiency (ASTM F2101)		99.1 - 99.8%	99.17%	Similar
Particulate Filtration Efficiency (ASTM F2299)		99.55 - 99.91 %	99.18%	Similar
Differential Pressure (EN 14683/MIL-M-36954C)		2.5 - 3.3 mm H_2O/cm^2	3.79 mm H_2O/cm^2	Similar
Flammability (16 CFR 1610)		Class 1	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 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 passed all acceptance criteria in the consensus standards as set forth in the Tables 2 and 3 below.

Table 2: Performance Testing

Testing Standards	Acceptance Criteria ASTM F2100 Level 1	Sovereign America Surgical Mask (K201095)	Predicate Device (K153409)
Fluid Resistance (ASTM F1862)	29 out of 32 passed at 80 mmHg	29 out of 32 passed at 80 mmHg	29 out of 32 passed at 80 mmHg
Bacterial Filtration Efficiency (ASTM F2101)	≥ 95%	99.1 - 99.8%	99.17%
Particulate Filtration Efficiency (ASTM F2299)	≥ 95%	99.55 - 99.91 %	99.18%
Differential Pressure (EN 14683/ MIL-M-36954C)	< 5.0 mm H_2O/cm^2	2.5 - 3.3 mm H_2O/cm^2	3.79 mm H_2O/cm^2
Flammability (16 CFR 1610)	Class 1	Class 1	Class 1

Table 3: Biocompatibility Testing

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

9. Conclusion:

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 K153409.