July 26, 2019

Air Techniques Inc.
Samir Ghevariya
Regulatory Affairs Specialist
1295 Walt Whitman Road
Melville, New York 11747

Re: K190949
Trade/Device Name: ScanX Barrier Envelopes
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape And Drape Accessories
Regulatory Class: Class II
Product Code: PEM
Dated: June 19, 2019
Received: June 20, 2019

Dear Samir Ghevariya:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*
K190949

Device Name
ScanX Barrier Envelopes

Indications for Use *(Describe)*
Disposable Barrier Envelopes are intended to be used as a disposable barrier for Air Techniques Phosphor Storage Plates. This device is non-sterile and intended for single patient use only.

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.

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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."

ScanX Barrier Envelopes Model Numbers (Attachment to the Indications for Use Statement- Form FDA 3881)		
Model (Part) Number:	**Device Description:**	**Device Size (In Inches):**
73248-0	ScanX Barrier Envelope; 100 Pcs/Box, Size #0	1.46 In x 0.96 In
73248-1	ScanX Barrier Envelope; 100 Pcs/Box, Size #1	1.68 In x 1.04 In
73248-2	ScanX Barrier Envelope; 300 Pcs/Box, Size #2	1.73 In x 1.32 In
73248-2k	ScanX Barrier Envelope; 1000 Pcs/Box, Size #2	1.73 In x 1.32 In
73248-3	ScanX Barrier Envelope; 100 Pcs/Box, Size #3	2.23 In x 1.16 In
73248-4	ScanX Barrier Envelope; 100 Pcs/Box, Size #4	3.20 In x 2.35 In
G8511-0	ScanX Side Loading Barrier Envelope; 100 Pcs/Box, Size #0	1.52 In x 0.98 In
G8511-1	ScanX Side Loading Barrier Envelope; 100 Pcs/Box, Size #1	1.67 In x 1.02 In
G8511-2	ScanX Side Loading Barrier Envelope; 300 Pcs/Box, Size #2	1.75 In x 1.34 In
G8511-2k	ScanX Side Loading Barrier Envelope; 1000 Pcs/Box, Size #2	1.75 In x 1.34 In
G8511-3	ScanX Side Loading Barrier Envelope; 100 Pcs/Box, Size #3	2.22 In x 1.14 In
G8511-4	ScanX Side Loading Barrier Envelope; 50 Pcs/Box, Size #4	3.09 In x 2.40 In

510(k) Summary, Air Techniques Inc.

ScanX Barrier Envelopes, K190949

The summary of 510(k) is being submitted in accordance with the requirements of 21 CFR §807.92

1. Date Summary Prepared:

July 22, 2019

2. Submitter's Identification:

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Website: www.airtechniques.com

Contact Information:

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Fax: +1-516-740-4622
Email: Samir.Ghevariya@airtechniques.com

3. Device Name:

Trade /Proprietary Name:	ScanX Barrier Envelopes
Device:	Dental barriers and sleeves
Regulation Number:	21 CFR 878.4370
Regulation description:	Surgical drape and drape accessories
Regulatory Class:	II
Product Code:	PEM
Review Panel:	Dental

4. Legally Marketed Predicate Device Information:

510(k) Number:	K163447

Manufacturer:	Premium Plus International Limited.
Trade /Proprietary Name:	Premium Plus Disposable Barrier Sleeve
Device:	Dental barriers and sleeves
Regulation Number:	21 CFR 878.4370
Regulation description:	Surgical drape and drape accessories
Regulatory Class:	II
Product Code:	PEM
Review Panel:	Dental

5. Device Description:

The ScanX barrier envelopes are made from one layer of clear blown polyethylene film and one layer of black blown polyethylene film heat sealed along three edges. An adhesive strip along the fourth edge is used for temporary barrier. Barrier Envelopes are used with Air Techniques' intraoral Phosphor Storage Plates. Barrier Envelopes are non-sterile, and disposable, single use only- discarded after each use.

6. Intended use/Indications for use:

Disposable Barrier Envelopes are intended to be used as a disposable barrier for Air Techniques Phosphor Storage Plates. This device is non-sterile and intended for single patient use only.

7. Device Models:

Model (Part) Number:	Device Description:	Device Size (In Inches):
73248-0	ScanX Barrier Envelope; 100 Pcs/Box, Size #0	1.46 In x 0.96 In
73248-1	ScanX Barrier Envelope; 100 Pcs/Box, Size #1	1.68 In x 1.04 In
73248-2	ScanX Barrier Envelope; 300 Pcs/Box, Size #2	1.73 In x 1.32 In
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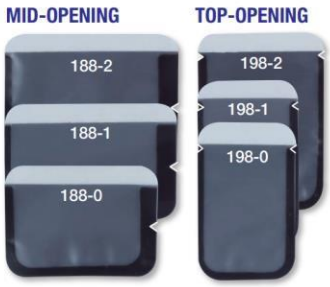
G8511-4	ScanX Side Loading Barrier Envelope; 50 Pcs/Box, Size #4	3.09 In x 2.40 In

8. Technological Characteristics:

Shown below is the technological characteristics comparison of the Air Techniques ScanX Barrier Envelopes with the Disposable Barrier Sleeves (predicate device).

Technological Characteristic Comparison Table

Comparison Criteria	**Predicate Device: Premium Plus Disposable Barrier Sleeves (K163447)**	**New Device: ScanX Barrier Envelopes (K190949)**	**Comparison**
Product Pictures			Similar
Intended Use	Premium Plus Disposable Barrier Sleeves are intended to be used as a disposable barrier for dental instruments and equipment. This device is non-sterile and intended for single patient use only.	Disposable Barrier Envelopes are intended to be used as a disposable barrier for Air Techniques Phosphor Storage Plates. This device is non-sterile and intended for single patient use only.	Same
Classification Product Code	PEM	PEM	Same

Material	Polyethylene film	Polyethylene film	Similar
Material Composition	Low density polyethylene and linear low density polyethylene film	Low density polyethylene	Similar
Biocompatibility	Non-cytotoxic Non-sensitizing Non-irritating	Non-cytotoxic Non-sensitizing Non-irritating	Similar
Film Thickness	0.03 mm	0.025 mm 0.027 mm 0.030 mm	Similar
Mechanical Properties	Tensile strength- tested in compliance with ASTM D882 Puncture resistance- tested in compliance with ASTM F1342 Tear resistance- tested in compliance with ASTM D1004	Tensile strength- tested in compliance with ASTM D882 Puncture resistance- tested in compliance with ASTM F1342 Tear resistance- tested in compliance with ASTM D1004	Similar
Sterility	Non-sterile	Non-sterile	Same
Single Use	Single use device	Single use device	Same
Performance Properties	Synthetic Blood Penetration- Pass Viral Penetration- Pass	Synthetic Blood Penetration- Pass Viral Penetration- Pass	Same
Dimensions	Determined by the size and shape of Phosphor Plates they cover	Difference in dimension is due to the size of Phosphor Storage Plates they cover	Similar
FDA Recognized Standards	ISO 10993-5 ISO 10993-10 ASTM F1670 ASTM F1671	ANSI/AAMI/ISO 10993-5:2009/(R2014) ISO 10993-10	Similar

	ASTM D882 ASTM F1342 ASTM D1004	ANSI/AAMI/ISO 10993-12:2012 ISO 10993-1:2018 ANSI/AAMI PB70:2012 ISO 14971:2007 ASTM F1670 ASTM F1671 ASTM D882 ASTM F1342 ASTM D1004 ISO 19232	

9. **Summary of Non-Clinical Data and Performance Testing:**
Shown below is a listing of the performance testing performed to demonstrate The functionality of the ScanX Barrier Envelopes.

Comparison Criteria	**Standards**	**Acceptance Criteria**	**Results**
Biocompatibility Testing:			
In-Vitro Cytotoxicity	ANSI/AAMI/ISO 10993-5	Score of Less Than 2	Pass
Sensitization	ISO 10993-10	Non-Sensitizer	Pass
Irritation	ISO 10993-10	Non-Irritant	Pass

Biological Risk Assessment	ISO 10993-1	Biological Safety	Pass
Performance and Mechanical Testing:			
Synthetic Blood Penetration	ASTM F1670/F1670M	Protective Materials Resistance Against Liquid Penetration	Pass
Viral Penetration	ASTM F1671/F1671M	Protective Materials Resistance Against Blood Borne Pathogens	Pass
Tensile Strength	ASTM D882	Tensile Properties of Material	Pass
Puncture Resistance	ASTM F1342	Protective Materials Resistance to Puncture/Rupture	Pass
Tear Resistance	ASTM D1004	Tear Resisting Ability	Pass
Image Quality	ISO 19232	Determination of Image Quality of Radiographs	Pass

The results from the non-clinical performance test demonstrated that the subject device met the acceptance criteria for each standard test performed.

10. Clinical Data:

NA

12. Conclusion:

The conclusions drawn from the nonclinical tests that demonstrate that the ScanX Barrier Envelopes is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K163447).