November 30, 2022

AeroClean Technologies, Inc.
% Rita King
CEO
MethodSense, Inc.
1 Copley Pkwy, Ste. 410
Morrisville, North Carolina 27560

Re: K223328
Trade/Device Name: Pūrgo™
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: October 27, 2022
Received: October 31, 2022

Dear Rita King:

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,

Christopher K. Dugard -S

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)*
K223328

Device Name
Pūrgo™

Indications for Use *(Describe)*
Pūrgo is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo is non-sterile.

Pūrgo has been demonstrated to remove the following organisms under the following exposure conditions:

Organism	Name	Avg. max log reduction / exposure time (min)
Gram + Bacteria	Methicillin resistant Staphylococcus epidermidis	*4.6 (45) at normal speed*
Gram + Bacteria	Bacillus globigii endospore	*4.1 (60) at normal speed*
Gram - Bacteria	Escherichia coli	*5.4 (45) at normal speed*
RNA Virus	MS2 bacteriophage	*5.4 (60) at normal speed*
RNA Virus	SARS-CoV-2	*4.2 (60) at normal speed*
DNA Virus	Phi-X174 bacteriophage	*4.4 (45) at normal speed*
Fungal Spore	Aspergillus brasiliensis spore	*4.3 (90) at normal speed*

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

K223328

AeroClean Technologies, Inc.

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: AeroClean Technologies, Inc.
10455 Riverside Drive, Suite 100
Palm Beach Gardens, FL 33410

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: 919-313-3961
Fax: 919-313-3979

Company Contact: Richard Foster
Title: Senior Director Quality and Regulatory Affairs
Email: rfoster@aeroclean.com
Phone: (773) 791-6198

Date Prepared: November 29, 2022

Trade Name: Pūrgo™

Common Name: Purifier, Air, Ultraviolet, Medical

Classification: Class II

Regulation Number: 21 CFR 880.6500

Classification Panel: General Hospital

Product Code: FRA

Predicate Device:

	Primary Predicate
Trade Name	Pūrgo™
Common Name	Purifier, Air, Ultraviolet, Medical
510(k) Submitter / Holder	AeroClean Technologies, Inc.
510(k) Number	K213753
Regulation Number	21 CFR 880.6500
Classification Panel	General Hospital
Product Code	FRA

The primary predicate device has not been subject to a design-related recall.

Device Description

Pūrgo™ is a free-standing air disinfection system employing two technologies for purifying air: HEPA filtration and UV-C light irradiation, removing or destroying bacteria and viruses in air. Pūrgo™ may be used in medical facilities and commercial home healthcare environments. Pūrgo™'s main components consist of:

- LED UV-C lamps that generate irradiation to destroy microorganisms that are not filtered;
- a proprietary SteriDuct chamber that intensifies the UV-C light to destroy microbiological material;
- a filtration system with pre-filter, activated carbon filter, and HEPA filter;
- a motor / impeller to move air through the filtration system;
- sensors to monitor UV irradiance and airflow;
- an electronic control system to power and control the device; and
- a touch panel interface equipped with LEDs to indicate the working status of the device.

Pūrgo™ has several built-in safety features that will prevent operation of the unit if the filter cartridge is not in place or if the filter door is not closed. The unit also incorporates UV and airflow sensors that provide warnings to the user if the device is not performing as designed to purify air.

Pūrgo™ pulls air through a filter cartridge and then passes the filtered air through a chamber containing UV-C light to neutralize remaining airborne microorganisms (such as bacteria, viruses, and fungi). The filter cartridge contains a series of three filters, the first of which is a pre-filter that removes physically large particulate matter (such as dust) and protects the finer particle filters downstream. This is followed by an Activated Carbon filter. Finally, a HEPA (high-efficiency particulate air) filter that removes 99.995% of the remaining airborne particles above a particle size of 0.1 µm.

Any microbes that still manage to make it through the filters, pass through the SteriDuct chamber where they are subjected to Ultraviolet Radiation at 265 nm (UV-C). UV radiation at this wavelength is particularly effective at destroying microbes. UV-C irradiation has been shown to damage the microbe's RNA and DNA genetic materials sufficiently to prevent the microbe's ability to reproduce.

After passing through the filtration and SteriDuct UV-C chamber, the purified air then exits back into the room. The exit air does not destroy laminar air flow in a typical operating room environment.

Indications for Use

Pūrgo™ is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo™ is non-sterile.

Pūrgo™ has been demonstrated to remove the following organisms under the following exposure conditions:

Organism	**Name**	**Avg. max log reduction / exposure time (min)**
Gram + Bacteria	Methicillin resistant Staphylococcus epidermidis	*4.6 (45) at normal speed*
Gram + Bacteria	Bacillus globigii endospore	*4.1 (60) at normal speed*
Gram - Bacteria	Escherichia coli	*5.4 (45) at normal speed*
RNA Virus	MS2 bacteriophage	*5.4 (60) at normal speed*
RNA Virus	SARS-CoV-2	*4.2 (60) at normal speed*
DNA Virus	Phi-X174 bacteriophage	*4.4 (45) at normal speed*
Fungal Spore	Aspergillus brasiliensis spore	*4.3 (90) at normal speed*

Summary of Technological Characteristics compared to Predicate Device

Characteristic	Subject Device Pūrgo™ (K223328)	Primary Predicate Device Pūrgo™ (K213753)	Comparison
Intended Use	To remove and destroy, by exposure to UV radiation, bacteria and viruses in interior spaces.	To remove and destroy, by exposure to UV radiation, bacteria and viruses in interior spaces.	**Identical**
Indications for Use	Pūrgo™ is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo™ is non-sterile. Pūrgo™ has been demonstrated to remove the following organisms under the following exposure conditions: Avg. max log reduction / exposure time (min): Methicillin resistant Staphylococcus epidermidis 4.6 (45) at normal speed Bacillus globigii endospore 4.1 (60) at normal speed Escherichia coli 5.4 (45) at normal speed MS2 bacteriophage 5.4 (60) at normal speed **SARS-CoV-2 4.2 (60) at normal speed** Phi-X174 bacteriophage 4.4 (45) at normal speed Aspergillus brasiliensis spore 4.3 (90) at normal speed	Pūrgo™ is a combination UV and air filtration device, equipped with UV-C LEDs and a True HEPA filter intended for the reduction of bacteria, virus, fungal spores, and particles in air for use in medical facilities and other indoor spaces. Pūrgo™ is non-sterile. Pūrgo™ has been demonstrated to remove the following organisms under the following exposure conditions: Avg. max log reduction / exposure time (min): Methicillin resistant Staphylococcus epidermidis 4.6 (45) at normal speed Bacillus globigii endospore 4.1 (60) at normal speed Escherichia coli 5.4 (45) at normal speed MS2 bacteriophage 5.4 (60) at normal speed Phi-X174 bacteriophage 4.4 (45) at normal speed Aspergillus brasiliensis spore 4.3 (90) at normal speed	**Equivalent** The subject device is also indicated for use in removing SARS-CoV-2. The safety and effectiveness of this additional indication for use has been demonstrated through microorganism performance testing.
User	Healthcare Professional Lay User	Healthcare Professional Lay User	**Identical**

Characteristic	Subject Device Pūrgo™ (K223328)	Primary Predicate Device Pūrgo™ (K213753)	Comparison
Environment of Use	Hospital and other healthcare setting. General Surgery Setting. Home healthcare.	Hospital and other healthcare setting. General Surgery Setting. Home healthcare.	**Identical**
Placement	Pūrgo™ will work in any room, but giving it a space in a central location is recommended. Placement near the patient is key. Pūrgo™ may be used in surgical suites. Pūrgo™ is designed for rooms up to 3000 ft^3.	Pūrgo™ will work in any room, but giving it a space in a central location is recommended. Placement near the patient is key. Pūrgo™ may be used in surgical suites. Pūrgo™ is designed for rooms up to 3000 ft^3.	**Identical**
User Control	Touch panel with selections for 3 fan speeds, power button, timer, and UV and airflow indicators.	Touch panel with selections for 3 fan speeds, power button, timer, and UV and airflow indicators.	**Identical**
Software	Basic Firmware; used to turn the unit on, off, change fan speed, and other administrative functions (timer, UV and airflow status).	Basic Firmware; used to turn the unit on, off, change fan speed, and other administrative functions (timer, UV and airflow status).	**Identical**
Mechanism of Action	Air is pulled through a multi-layer filter (pre-filter, activated carbon, HEPA) to remove microorganisms and then into a UV chamber (SteriDuct) containing UV-C light with sufficient energy to kill any remaining microorganisms.	Air is pulled through a multi-layer filter (pre-filter, activated carbon, HEPA) to remove microorganisms and then into a UV chamber (SteriDuct) containing UV-C light with sufficient energy to kill any remaining microorganisms.	**Identical**
Installation	Free standing	Free standing	**Identical**

Filter	Pūrgo™ Filter:
	• Multi-layer filter with 1/8” thick pre-filter, 1/8” thick activated carbon filter, and HEPA filter media
	• Dimensions: 16.5” x 19.5” x 2.5”
	• HEPA filter:
	  ○ Number of pleats: 140
	  ○ Depth of pleats: 42mm
	  ○ Minimum filter media area: 61 sq ft
		Pūrgo™ Filter:
		• Multi-layer filter with 1/8” thick pre-filter, 1/8” thick activated carbon filter, and HEPA filter media
		• Dimensions: 16.5” x 19.5” x 2.5”
		• HEPA filter:
		  ○ Number of pleats: 140
		  ○ Depth of pleats: 42mm
		  ○ Minimum filter media area: 61 sq ft
			Identical

Characteristic	Subject Device Pūrgo™ (K223328)	Primary Predicate Device Pūrgo™ (K213753)	Comparison
Light Source	• UV Type: UV-C • UV Light Source: LED • Wavelength: 265 nm • Total of 4 UV LEDs • Total UV Power: 110 mW • SteriDuct Irradiance: 0.24 mW/cm^2	• UV Type: UV-C • UV Light Source: LED • Wavelength: 265 nm • Total of 4 UV LEDs • Total UV Power: 110 mW • SteriDuct Irradiance (Minimum): 0.24 mW/cm^2	**Identical**
Air Source	Centrifugal Fan	Centrifugal Fan	**Identical**
Flow Control	Three speeds (sleep, normal, boost) provide minimum 125-315 CFM flow.	Three speeds (sleep, normal, boost) provide minimum 125-315 CFM flow.	**Identical**
Device Air Changes Per Hour (ACH)	1.875 – 2.36 device air changes per hour on Boost, 250 – 315 CFM, in a 1000 ft^2 room.	1.875 – 2.36 device air changes per hour on Boost, 250 – 315 CFM, in a 1000 ft^2 room.	**Identical**
Fan Exposure Safety Features	Diffuser panel on side of device and SteriDuct cover behind filter door to block user from accessing spinning fan without tools. Safety feature confirmed by UL 507.	Diffuser panel on side of device and SteriDuct cover behind filter door to block user from accessing spinning fan without tools. Safety feature confirmed by UL 507.	**Identical**
UV Light Exposure Safety Features	Safety interlock switch exists in filter door to ensure if the door is open or if a filter is missing, the unit will not operate. The purpose of these switches is to protect the user from any possibility of exposure to direct contact with UV light. Safety feature confirmed by UL 507.	Safety interlock switch exists in filter door to ensure if the door is open or if a filter is missing, the unit will not operate. The purpose of these switches is to protect the user from any possibility of exposure to direct contact with UV light. Safety feature confirmed by UL 507.	**Identical**
Input Voltage	120 Volt	120 Volt	**Identical**
Current	Up to 1.00 Amps	Up to 1.00 Amps	**Identical**
Power Consumption	Up to 120 Watts	Up to 120 Watts	**Identical**

Characteristic	Subject Device Pūrgo™ (K223328)	Primary Predicate Device Pūrgo™ (K213753)	Comparison
Dimensions	Unit Dimensions: 25.8”H (27.5” with casters) x 19.5”W x 10.6”D Filter Dimensions: 16.5” x 19.5” x 2.5”	Unit Dimensions: 25.8”H (27.5” with casters) x 19.5”W x 10.6”D Filter Dimensions: 16.5” x 19.5” x 2.5”	**Identical**
Standards	UL 507 Standard for Electrical Fans IEC 60601-1 Basic Safety and Essential Performance IEC 60601-1-2 EMC. EMC for Medical Devices IEC 60601-1-11 Home Healthcare Environment IEST-RP-CC001.6 HEPA and ULPA Filters	UL 507 Standard for Electrical Fans IEC 60601-1 Basic Safety and Essential Performance IEC 60601-1-2 EMC. EMC for Medical Devices IEC 60601-1-11 Home Healthcare Environment IEST-RP-CC001.6 HEPA and ULPA Filters	**Identical**

Summary of Non-Clinical Testing

The Pūrgo™ was verified and validated previously for submission K213753. The documented Verification & Validation plans and protocols demonstrated conformance with established performance criteria. This submission includes testing that was not available for the Pūrgo™ device. See below for the type of tests performed. AeroClean has completed the following testing:

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Microorganism Performance ***RNA Virus:*** ***SARS-CoV-2 testing performed***	Internal Standards	Testing was performed to evaluate the Pūrgo™'s efficacy against aerosolized biologicals. Testing was performed with the Pūrgo™ device in accordance with the normal use of the system (i.e. both the filtration and UV systems active at the normal speed) with seven (7) different aerosolized biologicals. Testing was performed with two aerosolized biologicals (MS2 and Bacillus globigii as they are representative of the more difficult biologicals to filter and destroy) at the sleep and boost fan speeds to demonstrate that the efficacy of the device isn't compromised by changes in fan speed. Additional testing was conducted using SARS-CoV-2 virus to confirm the testing for the previously tested MS2 single strand RNA viral category.	4 log reduction (99.99%)	<u>Average net log reduction / time</u> *Methicillin resistant Staphylococcus epidermidis*, 4.6 / 45 60 mins at normal *Bacillus globigii endospore*, 4.1 / 60 mins at normal, 4.4 / 60 mins at sleep, 4.2 / 45 mins at boost *Escherichia coli,* 5.4 / 45 mins at normal *MS2 bacteriophage*, 5.4 / 60 mins at normal, 4.3 / 60 mins at sleep, 4.5 / 45 mins at boost ***SARS-CoV-2*,** **4.2 / 60 mins at normal** *Phi-X174 bacteriophage*, 4.4 / 45 mins at normal *Aspergillus brasiliensis spore*, 4.3 / 90 mins at normal

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Fractional Efficiency *No additional testing necessary*	IEST-RP-CC001.6 – HEPA and ULPA Filters	Fractional efficiency testing was performed on the Pūrgo™ filter and the Pūrgo™ device itself per IEST-RP-CC001.6 TypeH test to determine the fractional efficiency percentage of particles of varying size ranges.	Per Standard	*Filter*: fractional efficiency percentage of 99.995% at 0.1-0.2 µm *Pūrgo™ Unit with Filter*: fractional efficiency percentage of 99.990% at 0.1-0.2 µm
UV Intensity *No additional testing necessary*	Not Applicable	The UV intensity performance of the Pūrgo™ units was verified to ensure the appropriate amount of UV irradiance is achieved in the SteriDuct.	≥ 0.240 mW/cm^2	Pass
UV Irradiance Exposure *No additional testing necessary*	American Conference of Governmental Industrial Hygienists (ACGIH) 2019 Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs)	UV radiation testing and evaluation was performed to measure the irradiance values at each wavelength between 200-400nm and determine the effective irradiance of the UV radiation to ensure UV exposure from the device is within safe limits.	Per Standard	Testing demonstrated that when operating in the normal condition (filter in place), the unit meets daily exposure limits (less than 0.1 $\mu W/cm^2$ for an 8 hour duration) and is considered part of the ANSI/IENSA RP-27.3-07 Exempt Risk Group
Ozone *No additional testing necessary*	UL 867 - Electrostatic Air Cleaners UL ECVP 2998 Zero Ozone Emissions for Air Cleaners, 3rd edition – 2020	Ozone testing was performed per UL 867 by monitoring the ozone concentration in a test chamber at the highest fan speed and lowest fan speed.	Per Standard	Testing demonstrates the Pūrgo™ unit is able to operate at less than 0.005 ppm at its highest and lowest fan speed.

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Airflow Performance Evaluation *No additional testing necessary*	Not Applicable	The airflow performance of the Pūrgo™ units was verified at the three fan speeds available to the user.	Sleep: min. 125 CFM Normal: min. 200 CFM Boost: min. 315 CFM	Pass
Laminar Airflow Evaluation *No additional testing necessary*	Internal Standards	Computational fluid dynamics (CFD) was performed to evaluate airflow from the Pūrgo™ unit in a prototypical surgery room with the aim of determining combinations of Pūrgo™ unit positions and operating conditions that preserves the stable air curtain over the surgery table (i.e. does not disturb laminar flow). Flow rate, placement, and HVAC return duct position were considered in the analysis and	Pūrgo™ does not disturb laminar flow	Testing determined that optimal placement was near the outer wall of room (8' from the surgery table) for Pūrgo™ flow rates of 230 to 315 CFM. This is true regardless of whether HVAC return ducts were located near the ceiling or floor of the room.

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Home Healthcare Environments *No additional testing necessary*	FDA Guidance "Design Considerations for Devices Intended for Home Use" (November 24, 2014) IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; 2012 IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment; 2015	FDA's Guidance "Design Considerations for Devices Intended for Home Use" (November 24, 2014) was followed for the design and development of Pūrgo™ to ensure the home use device complies with applicable standards of safety and effectiveness and other regulatory requirements.	Per Standards	Pass
Electrical Safety *No additional testing necessary*	UL 507: Standard for Electric Fans IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; 2012	Electrical safety testing was performed in accordance with UL 507 and IEC 60601-1.	Per Standard	Pass

Test Name	Applicable Standards	Purpose	Acceptance Criteria	Results
Electromagnetic Compatibility *No additional testing necessary*	IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests; Edition 4.0	Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2.	Per Standard	Pass
Software Validation *No additional testing necessary*	FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005)	Software verification and validation testing was performed for the Pūrgo™ device firmware.	Meet defined specifications	Pass

Summary Clinical Testing

No clinical tests were required to demonstrate substantial equivalence.

Conclusion

The conclusions drawn from the nonclinical testing demonstrate that the subject device, Pūrgo™ is as safe, as effective, and performs as well as or better than the legally marketed predicate, K213753 Class II (21 CFR 880.6500), product code FRA.