Exact Medical Manufacturing
℅ Abdel Halim, PharmD, MSc, PhD, DABCC
President, Global Quality and Regulatory Services
Global Quality and Regulatory Services
10 Scenic Way
MONROE, NEW JERSEY 08831

August 13, 2021

Re: K211969
Trade/Device Name: EMM Ultrasonic Transducer Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: August 10, 2021
Received: August 12, 2021

Dear Dr. Halim:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K211969

Device Name
EMM Ultrasonic Transducer Cover

Indications for Use *(Describe)*
Exact Medical Manufacturing Ultrasonic Transducer Cover can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for external intact skin. This may help with easier cleaning and disinfection of the probe. This product is not intended for use of probes with endocavity or intraoperative use. The Exact Medical Manufacturing Ultrasonic Transducer Cover are also sold as bulk non-sterile, single use items, to repackager/ relabeler establishments for further packaging and ethylene oxide sterilization.

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 for Exact Medical Manufacturing Inc., EMM Ultrasonic Transducer Cover

Date Summary was Prepared	March 31, 2021
510(k) Submitter	Ryan Power, Vice President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 kpower@exactmm.com (p)716-681-0866, (f) 716-681-4110
Primary Contact for this 510(k) Submission	Ryan Power, Vice President Exact Medical Manufacturing Inc. 4917 William Street, Suite C Lancaster, NY 14086 kpower@exactmm.com (p)716-681-0866, (f) 716-681-4110
Device Common Name	Cover, Ultrasonic Transducer Cover
Trade Name	Cover, Disposable,
Device Product Codes and Classification Name	Diagnostic ultrasonic transducer ITX, 21CFR892.1570, Class II
Predicate Device	MedXPress Pro, EZ-Cover K 191491
Device Description	A 0.05mm thin, 50 GSM (Grams per Square Meter), translucent high strength polyurethane film tube shape, nominally 48" x 6" with heat sealed distal end to be applied over a transducer probe to provide a Transducer Cover that can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for external intact skin. This may help with easier cleaning and disinfection of the probe. This product is not intended for use of probes with endocavity or intraoperative use. The Exact Medical Manufacturing Ultrasonic Transducer Cover are also sold as bulk non-sterile, single use items, to repackager/relabeler/kit packers establishments for further packaging and ethylene oxide sterilization.
Indications for Use	Exact Medical Manufacturing Ultrasonic Transducer Cover can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for external intact skin. This may help with easier cleaning and disinfection of the probe. This product is not intended for use of probes with endocavity or intraoperative use. The Exact Medical Manufacturing Ultrasonic Transducer Cover are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.
Technological Characteristics	Exact Medical Ultrasonic Transducer Cover has the same design, material, and performance characteristics of the predicate device.
Summary of Non-Clinical Testing	Exact Medical Ultrasonic Transducer Cover is substantially equivalent and meets the same acceptance criteria as the predicate device as in K191491. Non-clinical performance testing includes; • barrier properties- AAMI PB70, Level 3, • tensile • elongation • flammability • linting, • sterility • biocompatibility • acoustics performance. • ethylene oxide residuals All results of the testing met acceptance criteria. See following (below) Summary Tables.
Clinical Testing	None, not applicable
Substantial Equivalence Conclusion	The transducer cover described in this 510(k) submission are substantially equivalent in all specifications and performance compared to the predicate device identified in K191491 except for minor variations in the widths and lengths. There are no significant differences among the submission device and the predicate device which present concerns concerning safety and effectiveness.

Bench Testing Summary

Test Performed & Description of test	Device Description / Sample Size	Reference Standard	FDA Recognition number or Not Recognized (NR)	Acceptance Criteria	Unexpected Results/ Significant Deviations	Result Summary	Conclusion
Water Resistance: Impact Penetration Test, Level 3	Final Finished Device (both heat seal and TPU film). Worst case, largest size in the submission. Sample Size N= 32 with C=0 AAMI PB70 Sample Size AQL of 4 %/RQL of 20 %. Test sample exceeds the reference standard requirements (N=32, C=3)	AATCC 42:2017 (AAMI PB70:2003 /(R)2009)	NR	blotter weight gain of no more than 1.0 g	None	Accept 32 samples =/< 1.0g (all samples = 0.0 g)	Ability of a protective product to resist the penetration of liquids and liquid borne Microorganisms accordingly to AAMI PB70, Level 3 Substantially equivalent barrier property compared to the predicate device
Test Method for Water Resistance: Hydrostatic Pressure Level 3	Final Finished Device (both heat seal and TPU film). Worst case, largest size in the submission. Sample Size N= 32 with C=0 AAMI PB70 Sample Size AQL of 4 %/RQL of 20 %. Test sample exceeds the reference standard requirements (N=32, C=3)	AATCC 127:2017 (2018)e (AAMI PB70:2003 /(R)2009)	NR	hydrostatic resistance of at least 50 cm	None	Accept 32 samples > 50cm (all samples =/> 180cm)	Ability of a protective product to resist the penetration of liquids and liquid borne Microorganisms accordingly to AAMI PB70, Level 3 Substantially equivalent barrier property compared to the predicate device
Flammability of Clothing Textiles	Polyurethane Film Sample Size per 16CFR1610, 5 replicates are to be tested if no flame spread is observed upon preliminary testing. Material evaluation only for flammability, not relevant to device configuration.	16CFR1610	NR	Burn Time >/= 3.5 seconds	None	Accept 5 samples DNI (Did Not Ignite)	Able to meet and claim flammability Class 1 rating in accordance with 16CFR1610 Exceeds predicate device based upon predicate device has not been tested for this attribute.
Determination of tensile properties — Part 3: Test conditions for films and sheets (Tensile and Elongation)	Polyurethane Film Material evaluation only, not relevant to device configuration. Sample size per statistical sampling plan ISO2859-1, based upon lot population quantity	ISO 527-3	NR	Tensile strength minimum 40N in machine direction Tensile strength minimum 34N in cross direction Elongation 108 % minimum in machine direction Elongation 119% minimum in cross direction	None	Accept All samples must pass acceptance criteria in accordance with statistical sampling plan per ISO2859-1, otherwise, material is rejected (not used in production)	Specification confirmation of tensile and elongation properties of plastic films or sheets less than 1 mm thick to assure compliant device barrier performance. Substantially equivalent tensile and elongation property compared to material specification .
Lint and other particles generation in the dry state	Polyurethane film Material evaluation only, not relevant to device configuration. Sample size = 10 Standard indicates 5 samples	ISO 9073-10	NR	IPM =/< 3.5 (Index for Particle Matter)	None	Accept IPM 1.3 (outside) IPM 0.72 (inside)	Material does not significantly generate lint or particles that may shed during an ultrasonic scan procedure. Exceeds predicate device based upon predicate device has not been tested for this attribute.
Acoustic Output Measurement Standard for Diagnostic Ultrasound	Final Finished Device Worst case test configuration on distal sealed end where ultrasonic probe is positioned. Polyurethane 50gsm tested.	NEMA UD 2-2004 (R2009)	12-105	negligible effect on the transmission of ultrasound signal and does not degrade signal or image	None	Accept Speed of sound = 1698 m/sec Acoustic Attenuation = 0.51 dB	Based on the acoustic testing results it was concluded that EMM's transducer/probe cover has negligible effect on the transmission of ultrasound signal and that EMM's transducer/probe

Equipment, Revision 3	Sample size 3 ea. Speed of Sound 3 ea. Acoustic Attenuation 3 ea. Acoustic Impedance					Acoustic Impedance = 1.63 MRayl	cover does not degrade signal or image. Exceeds predicate device based upon predicate device has not been tested for this attribute.
Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents. Compatibility of ultrasonic coupling gel with polyurethane	Polyurethane Probe Cover Samples Sample Size N=45 Tested by Manufacturer of coupling gel, FDA 510K cleared K130581. This element is not an Exact Medical Manufacturing product. Bench Testing is provided to confirm compatibility with polyurethane film	ASTM D543-20	NR	Evaluated for Color, Dimension, Weight, Coordinates, Mechanical Properties. Acceptance Criteria Not Defined	None	Accept Color N=9, Pass, Dimension N=9 Pass, Weight N=9 Pass, Coordinates N=9 Pass, Mechanical Properties N=9 Pass	Confirmation that device polyurethane material is not negatively affected by the acoustic coupling gel during an ultrasonic scanning procedure. Exceeds predicate device based upon predicate device does not provide compatibility evaluation of acoustic coupling gel with their device.
Ethylene Oxide Residuals	Polyurethane film Worst case, Run the sterilization cycle at the cycle parameters which provide for the highest EO exposure, i.e. high gas induction time and pressure (most pounds of EO), highest length of EO dwell time, least time for post cycle vacuums, lowest amount of aeration time within aeration chamber. Sample Size per sterilization batch N=15 X 3 consecutive sterilization batches = 45 samples	ISO 10993-7:2008,	14-408	tolerable contact limit (TCL) as expressed in units of micrograms per square centimeter for EO at 10ug/cm2 and milligrams per square centimeters for ECH at 5mg/cm2	None	Accept Actual results for EO Residuals at Time 0 hours = 8.67ug/cm2. Actual results for ECH residuals at Time 0 hours = Not detected (within the limits of detection of 3.7ug/g).	Confirmation of maximum allowable residues for ethylene oxide (EO) within the submission device sterilized with EO and to ensure that the levels of residual EO, ethylene chlorohydrin (ECH) and ethylene glycol (EG) pose a minimal risk to the patient in normal product use. Substantially equivalent to predicate device based upon acceptable testing results that comply with testing standard.
In Vitro Cytotoxicity Test	The test article. Probe Cover polyurethane, EO Exposed, was evaluated to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L929 cells) in response to the test article. Sample Size = 4 test article extracts	ISO 10993-5;2009	2-245	The lower the Viab.% value, the higher the cytotoxic potential of the test article is. If viability is reduced <70% of the blank, it has cytotoxic potential. The Viab.% of 100% extract of the test article is the final result	None	100% Test article extract 76.5% viability. No Test article extracts are <70% viability.	Testing Conducted on final sterilized device. Study conclusion, “Under the conditions of this study, the test article extract did not show potential toxicity to L929 cells

Performance Testing – Animal Summary Table:

Test protocol description.	Results Summary	Analysis	Conclusion	Objective of test	Test Article	Test method and procedure	Study endpoint	pre-defined acceptance or pass/fail criteria
ISO 10993-10:2010:2010 Closed patch Sensitization Study in Guinea Pigs	No skin sensitization reaction was found in the Guinea pigs using extracts of the test article (0.9% sodium chloride, sesame oil). The positive rate of sensitization was 0%.	Dermal Reactions Challenge <u>24 Hour Score</u> Ten test Guinea pigs, 0 (zero) reactions <u>48 Hour Score</u> Ten test Guinea pigs, 0 (zero) reactions	Under the conditions of the study, the test article extracts showed no significant evidence of causing skin sensitization in the Guinea pigs.	The purpose of this study was to evaluate the potential of the test article to cause dermal contact sensitization following repeated occlusive patching in the guinea pig.	Probe cover Polyurethane	This study was conducted to evaluate skin sensitization using Guinea pig maximization test based on the ISO 10993-10:2010:2010, Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization.	The test article. Probe Cover polyurethane, EO Exposed, was evaluated for the, was evaluated for the potential skin sensitization in the Guinea pig.	No significant evidence of causing skin sensitization in the guinea pig. Applying grading scales as follows, No visible change = 0 Discrete or patchy erythema = 1 Moderate and confluent erythema =2 Intense erythema and swelling = 3 Substantially equivalent to the predicate device based upon meeting the acceptance criteria of the test standard to evaluate the potential of the test article to cause dermal contact sensitization following repeated occlusive patching in the guinea pig
ISO 10993-10:2010:2010 Intracutaneous Reactivity Test	All animals were survived and no abnormal signs were observed during the study. According to what observed,	Summary Analysis Test Results of Dermal Observations in Test Article <u>Extract SC</u> 24 hr = 0	The test result showed that the polar and non-polar extract of the final test sample score is less 1.0, the requirements of the test are met.	To evaluate the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbit and extrapolating the	Probe cover Polyurethane	To evaluate the potential intracutaneous reactivity caused by intracutaneously inject the extract to rabbit in accordance with	The test article. Probe Cover polyurethane, EO Exposed, was evaluated for the Intracutaneous Reactivity Test	The requirements of the test are met if the final test article score is 1.0 or less. Substantially equivalent to

	the skin reaction of polar and non-polar extract on testing side did not exceed that on the control side. Thus, the final test article score was calculated to be 0. See table 3.	48 hr = 0 72 hr = 0 <u>Extract SO</u> 24 hr = 0 48 hr = 0 72 hr = 0		results to humans, but it does not establish the actual risk of irritation.		ISO l 0993-10:2010 Biological evaluation of medical devices - Part I0: Tests for irritation and skin sensitization.	in New Zealand white rabbits.	the predicate device based upon meeting the acceptance criteria of the test standard to evaluate the potential intracutaneous reactivity

510K Summary: Submission Device to Predicate Device Comparison

Exact Medical Manufacturing – Transducer Cover	Substantially Equivalent	MedXPress.Pro EZ-Cover K191491 PREDICATE DEVICE
Indications for Use: Exact Medical Ultrasonic Transducer Cover can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for external intact skin. This may help with easier cleaning and disinfection of the probe. This product is not intended for use of probes with endocavity or intraoperative use. The Exact Medical Manufacturing Ultrasonic Transducer Cover are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and ethylene oxide sterilization.	Substantially Equivalent	**Indications for Use**: Probe cover can be used to minimize contamination between patient and ultrasound probe during ultrasound scanning procedures for external intact skin. This may help with easier cleaning and disinfection of the probe. This product is not intended for use of probes with endocavity or intraoperative use.
Classification & Code Classification & Code Diagnostic ultrasonic transducer ITX, 21CFR892.1570, Class II	Substantially Equivalent	**Classification & Code** Diagnostic ultrasonic transducer ITX, 21CFR892.1570, Class II
Barrier properties - AATCC 42:2007, AATCC 127:2008: Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for Use in Health Care Facilities, AAMI PB70:2003 /(R)2009, **Level 3, AATCC 42 ≤ 1.0 g, AATCC 127 ≥ 50 cm**	Substantially Equivalent	Water Resistance Polyethylene film can withstand xx hydrostatic pressure time should not be less than xx. Standards not indicated
Materials & Construction: POLYMER, Polyurethane, tubular, sealed	Substantially Equivalent	Materials & Construction: POLYMER, Polyethylene, tubular, sealed
Sterile (via EO Gas) ISO 11135-1:2014, Sterilization of health care products - Ethylene oxide - Part 1. SAL 10^{-6}	Substantially Equivalent	Sterilization Validation (Re-validation of Report of Ethylene Oxide Sterilizer Performance)
Sterile Barrier Packaging: Chevron peel pouch (coated paper (73gsm), PET12/PE40 film construction), individual internal wrap.	Substantially Equivalent	Aseptic packaging seal test
Disposable, Single Use Only	Substantially Equivalent	Disposable, Single Use Only
Non-Sterile, Bulk Pack		Not offered
Tensile strength Machine Direction / Cross Direction – ISO 527- 3 Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets Machine Direction / Cross Direction: 40N per 2.5cm / 34N per 2.5cm	Substantially Equivalent	The maximum tensile strength of polyethylene film for manufacture protective sleeve should be no less than XX, and the maximum tensile force of traverse fracture is no more than XX Test Standard not Indicated
Elongation - – ISO 527- 3 Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets Machine Direction / Cross Direction: 108% / 119%	Substantially Equivalent	The rupture elongation of the film making the protective sleeve should be no less than xx% Test Standard not Indicated
Cover Acoustic Test - NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. Negligible effect on the transmission of ultrasound signal , transducer/probe cover does not degrade signal or image**.**	Exceeds predicate	Not indicated
Acoustics Coupling Gel: FDA Cleared via K130581 Reference Device: Exact Medical Manufacturing (EMM) intends to include a "sachet" of acoustic coupling gel. EMM does not perform any formulation, labeling or unit packaging for this acoustic coupling gel. The acoustic	Exceeds Predicate	Not indicated

coupling gel is provided private labeled and ready to use by the manufacturer and 510k holder of the acoustic coupling gel. The rationale that justifies its use is based upon the cleared 510K K130581Indications for Use for the acoustic coupling gel with EMM Ultrasonic Transducer Cover (from K130581, "Indications for Use: As stated on Label: Contact medium for ultrasonic and electrical transmission gel. Konix Sterile Gel is sterilized by gamma irradiation and intended for use in all diagnostic ultrasound procedures that currently use an ultrasound coupling gel or other fluid, alone or in **combination with a transducer cover**, where sterility and in vivo biocompatibility are required. It can be used on the skin where the risk for infections is especially high, especially with open tissue Doppler applications; and can be used for cystoscopic and vaginal Doppler and ultrasound examinations. Konix® Sterile Gel **can be used on the skin** or in open tissue where there is a risk for infections, such as in open tissue Doppler applications. It can be used during surgery; for cystoscopic and vaginal ultrasound and Doppler examinations; for cardiac surgery and ultrasound procedures; and as a lubricant in biopsy applications") remains identical as stated in 510K K130581.		
Biocompatibility: Cytotoxicity – ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity. **Non-Cytotoxic**	Substantially Equivalent	**Biocompatibility: Cytotoxicity –** ISO 10993-5, Biological evaluation of medical devices — Part 5: MEM Elution - Pass
Biocompatibility: Skin Irritation – ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization. **Categorized as Negligible**	Substantially Equivalent	**Biocompatibility: Skin Irritation** – ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization. Reactivity Irritation Test in Rabbits - Pass
Biocompatibility: Sensitization – ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization. **No evidence of causing delayed dermal reaction at 24h and 48h.**	Substantially Equivalent	**Biocompatibility: Sensitization –** ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization. Guinea Pig Maximization Sensitization Test - Pass
Flammability of Clothing Textiles - 16CFR1610:2010. Class 1 rating	Exceeds Predicate	Not indicated
Lint and other particles generation in the dry state - ISO 9073-10:2003. **Index for Particulate Matter(IPM) =/< 1.30**	Exceeds Predicate	Not indicated
Shelf Life: 5-year shelf life both accelerated stability studies and real time stability studies. Testing and evaluation inclusive of, dimensional, basis weight, tensile, elongation, melt index, surface resistance, tensile strength of heat seal, sterile barrier packaging.	Substantially Equivalent	Shelf life: shelf life time not indicated. Accelerated aging testing was performed in support of the EZ-Cover. Accelerated Aging Test Summary Accelerated Aging Test Report – Sterility Test Accelerated Aging Test Report -Aseptic Packaging Seal Test
Ethylene Oxide Residuals - ISO 10993-7:2008, Ethylene Oxide Sterilization Residuals Results of these tests indicate the EO residual amounts are below the tolerable contact limit (TCL) as expressed in units of micrograms per square centimeter for EO at 10ug/cm2 and milligrams per square centimeters for ECH at 5mg/cm2 (the acceptance criteria). Actual results for EO Residuals at Time 0 hours = 8.67ug/cm2.Actual results for ECH residuals at Time 0 hours = Not detected (within the limits of detection of 3.7ug/g).	Substantially Equivalent	If the protective sleeve is sterilized by ethylene oxide the residual ethylene residue should be less than XX ug/g at the factory

"Not indicated, Exceeds Predicate" explanation discussion specific to, • Cover Acoustic Test , • Acoustics Coupling Gel: FDA Cleared via K130581, • Flammability of Clothing Textiles, • Lint and other particles generation in the dry state	Explanation Discussion	A formal written request pursuant to 21CFR807.93(a)(1), "A 510(k) statement submitted as part of a premarket notification…" was sent to the submitter of 510K K191491 (the predicate, MedXPress.Pro, EZ-Cover). The reference regulation 21CFR807.93(a)(1) requires "…will make available all information included in this premarket notification on safety and effectiveness within 30 days of reque20st by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information…". The predicate device submitter made available all information included in this premarket notification on safety and effectiveness. The information as provided by the predicate 510K submitter does not include • Cover Acoustic Test , • Acoustics Coupling Gel: FDA Cleared via K130581 • Flammability of Clothing Textiles • Lint and other particles generation in the dry state On this basis and in accordance with the predicate submitter compliance to 21CFR807.93(a)(1) and Truth and Accuracy signed certification (21 CFR 807.87(l), all 510(k)s must include a statement certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted) there if no • Cover Acoustic Test , • Cover Acoustic Test , • Acoustics Coupling Gel: FDA Cleared via K130581 • Flammability of Clothing Textiles •Lint and other particles generation in the dry state , testing for the predicate device and the submission device (EMM Ultrasonic Transducer Cover) has • Cover Acoustic Test , • Acoustics Coupling Gel: FDA Cleared via K130581, • Flammability of Clothing Textiles • Lint and other particles generation in the dry state the submission device exceeds the predicate device