May 12, 2023

Exact Medical Manufacturing
% Madison Wheeler
Director of Technical Operations
EMMA International Consulting Group
30150 Telegraph Rd., Suite 120
BINGHAM FARMS MI 48025

Re: K222460
Trade/Device Name: Intraoperative Ultrasound Probe Cover
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: ITX
Dated: August 5, 2022
Received: April 10, 2023

Dear Madison Wheeler:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K222460

Device Name
Intraoperative Ultrasound Probe Cover

Indications for Use *(Describe)*
Intraoperative Ultrasound Probe Cover can be used to minimize contamination between the patient and the probe during ultrasound scanning procedures for both intact skin and compromised tissue. The cover allows use of the transducer in scanning and needle guided procedures for body surface, Endo cavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

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 – Traditional 510(k) K222460

A summary of information in accordance with requirements of 21 CFR 807.92.

SUBMITTER'S INFORMATION

Sponsor: Exact Medical Manufacturing

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Date Summary Prepared: April 01, 2023

DEVICE INFORMATION

Name of Device: Intraoperative Ultrasound Probe Cover
Common Name: Invasive Probe Cover
Classification Name: 892.1570 Diagnostic Ultrasonic Transducer
Product Code: ITX
Device Classification: Class II

Predicate Device

The proposed Invasive Prove Cover is substantially equivalent to the following predicate device:

Predicate Device	Manufacturer
Non-Pyrogenic CIV Flex – Non-Pyrogenic Ultrasound Transducer Cover K131528	CIVCO Medical Instruments Co., Inc

Device Description:

Intraoperative Ultrasound Probe Cover can be used to minimize contamination between the patient and the probe during ultrasound scanning procedures for both intact skin and compromised tissue. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

The probe cover is designed for use in both invasive and non-invasive procedures. It comes in a sterile form only. The sterile cover made used in invasive procedures where it will come into direct contact with compromised tissue. The probe cover may be used with any multiple

different probes including, but not limited to, an Endoscope, Endoscope re-usable, any rectal, vaginal, trans-urethral, gastro-entero probes, or pulmonary probe, In-vitro Fertilization instruments, biopsy probes, fiberoptic probes, catheter probes, any probe that is used during a surgical procedure, re-usable vascular (visualization) probes, and re-usable central nervous system (CNS) or cerebral probes.

Indications for Use:

Intraoperative Ultrasound Probe Cover can be used to minimize contamination between the patient and the probe during ultrasound scanning procedures for both intact skin and compromised tissue. The cover allows use of the transducer in scanning and needle guided procedures for body surface, Endo cavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.

Technological Characteristics:

No technological characteristics have changed between the proposed device and predicate devices. Both the predicates and the proposed device are comprised of equivalent materials.

Comparison to Predicate Devices:

Intraoperative Ultrasound Probe Cover has the equivalent intended uses and is subject to the same regulation as the CIVCO Medical Instruments Non-Pyrogenic CIV Flex (K131528):

Description	Intraoperative Ultrasound Probe Cover	PREDICATE DEVICE CIVCO Medical Instruments – Non-Pyrogenic CIV-Flex
Indications for Use	Intraoperative Ultrasound Probe Cover can be used to minimize contamination between the patient and the probe during ultrasound scanning procedures for both intact skin and compromised tissue. The cover allows use of the transducer in scanning and needle guided procedures for body surface, Endo cavity, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer.	Protective cover or sheath placed over diagnostic ultrasound transducer / probe / scan head instruments. The cover allows use of the transducer in scanning and needle guided procedures for body surface, endocavity, central nervous system, and intra-operative diagnostic ultrasound, while helping to prevent transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker during reuse of the transducer. The cover also provides a means for maintenance of a sterile field. The cover is single use patient / procedure, non-pyrogenic, and disposable.
Classification and Code	Polyurethane Probe Cover ITX, 21CFR892.1570, Class II	Non-Pyrogenic CIV Flex ITX, 21CFR892.1570
Material of Construction	POLYMER, Polyurethane, tubular, sealed	Polyurethane (CIV-Flex TM) and polyethylene
Sterile (via EO Gas)	ISO 11135-1:2014, Sterilization of health care products - Ethylene oxide - Part 1. SAL 10-6	EtO method. SAL 10-6. Non-pyrogenic. Endotoxin Method: LAL Kinetic Method (Chromogenic). Endotoxin Release Specification: 2.15 EU/device.

USE	Disposable, Single Use Only	Single use, non-pyrogenic, and disposable

Non-Clinical Testing:

The Intraoperative Ultrasound Probe Cover is substantially equivalent and meets the same acceptance criteria as the predicate device as in K131528. Non-clinical performance testing was conducted for the following barrier properties, tensile, elongation, linting, sterility, biocompatibility, acoustics performance, ethylene oxide residuals, bacterial endotoxins, viral penetration, water resistance/hydrostatic pressure, water resistance/impact penetration, and synthetic blood penetration. All results of the testing met acceptance criteria. Sterility, packaging, shelf life, biocompatibility, and performance testing completed on the predicate devices remains applicable for the proposed device and this testing is summarized in the submission.

Conclusions:

This premarket submission for the Intraoperative Ultrasound Probe Cover has demonstrated substantial equivalence to the CIVCO Medical Instruments Non-Pyrogenic CIV Flex as defined and understood in the Federal Food, Drug and Cosmetic act and various guidance documents issued by the Center for Devices and Radiological Health. Based on comparison against predicate devices and endotoxin testing, the Intraoperative Ultrasound Probe Cover is safe and effective for its intended use.