August 15, 2024

Parker Laboratories, Inc.
Candy Beck
Regulatory Specialist
286 Eldridge Road
Fairfield, New Jersey 07456

Re: K233965
Trade/Device Name: UltraDrape UGPIV Barrier and Securement (34-15)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, KGX
Dated: July 19, 2024
Received: July 19, 2024

Dear Candy Beck:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233965

Device Name

UltraDrape UGPIV Barrier and Securement (34-15)

Indications for Use *(Describe)*

UltraDrape UGPIV Barrier and Securement, a sterile, single-use disposable device, serves as a sterile, viral barrier when used in conjunction with ultrasound transducers to shield patients from the potential transfer of contaminants and biological risk agents that may be introduced during ultrasound scanning and needle-guided procedures. It also serves as a transparent dressing to protect and secure devices to the patient's skin when required. UltraDrape UGPIV Barrier and Securement is indicated for adults and pediatric patients. For use by healthcare professionals appropriately trained in ultrasound within healthcare settings utilizing ultrasound.

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) #: K233965

510(k) Summary

Prepared on: 2024-08-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Parker Laboratories, Inc.
Applicant Address	286 Eldridge Road Fairfield NJ 07456 United States
Applicant Contact Telephone	973.276.9700
Applicant Contact	Ms. Candy Beck
Applicant Contact Email	cbeck@parkerlabs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UltraDrape UGPIV Barrier and Securement (34-15)
Common Name	Diagnostic ultrasonic transducer
Classification Name	Transducer, Ultrasonic, Diagnostic
Regulation Number	892.1570
Product Code	ITX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221278	Hony Medical Co. Transducer Probe Covers	ITX
N/A	UltraDrape UGPIV Barrier and Securement	KGX

Device Description Summary

21 CFR 807.92(a)(4)

UltraDrape UGPIV Barrier and Securement is a uniquely designed, sterile, dual-action barrier and securement dressing designed for use during Ultrasound-Guided Peripheral Intravenous (UGPIV) procedures. UltraDrape is 3.25"(8.25 cm) wide x 5.8" (14.72 cm) long. UltraDrape UGPIV Barrier and Securement is sterile, nonirritating, non-sensitizing and is not made with natural rubber latex.

Ultrasound imaging is not impaired by use of UltraDrape UGPIV Barrier and Securement as it is intended. The ultrasound gel is applied to a removable Polyurethane film layer to prevent contamination of the injection site. Convenient adhesive strips on the release film provide added securement of tubing and catheter hub surround. The bifurcated, "stand-alone" design prevents gel from reaching the IV site while enabling seamless catheter insertion and securement.

UltraDrape UGPIV Barrier and Securement is furnished in sterile condition, for single use patient/procedure use, disposable. UltraDrape UGPIV Barrier and Securement is used with commercially available ultrasound probes.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

UltraDrape UGPIV Barrier and Securement, a sterile, single-use disposable device, serves as a sterile, viral barrier when used in conjunction with ultrasound transducers to shield patients from the potential transfer of contaminants and biological risk agents that may be introduced during ultrasound scanning and needle-guided procedures. It also serves as a transparent dressing to protect and secure devices to the patient's skin when required. UltraDrape UGPIV Barrier and Securement is indicated for adults and pediatric patients. For use by healthcare professionals appropriately trained in ultrasound within healthcare settings utilizing ultrasound.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The proposed device UltraDrape UGPIV and the predicate device Transducer Probe Cover have the following similarities:

• Both devices are single use, prescription-only devices intended to be used during needle-guided ultrasound procedures.
• Both protect patients against the transmission of biological risk agents and contaminants.
• The Instructions For Use for both devices include methods for safe disposal, safe storage and a warning not to use the product if damaged.

The proposed device UltraDrape UGPIV and the predicate device Transducer Probe Cover have the following differences:

• The predicate's Intended Use discusses protecting healthcare workers against the transmission of biological risk agents and contaminants; however, UltraDrape UGPIV covers the patient's skin, and therefore protects both the health care workers and the patient from the transfer of contaminants and biological risk agents. Thus, the intended use is substantially equivalent: protection from contaminants and biological risk agents.
• The specific application instructions included in the Instructions For Use of these devices are different in order to accommodate the Transducer Probe Cover being applied to the probe while UltraDrape UGPIV is applied directly to the patient. However, the devices are substantially equivalent because the instructions lead to application consistent with equivalent intended uses.
• The proposed device UltraDrape UGPIV IFU provides a warning that the probe cover should not be resterilized, while the predicate device Transducer Probe Cover IFU does not. Since both devices are indicated as single use, and both should be discarded if damaged, resterilization is not indicated in either case.
• The predicate device Transducer Probe Cover IFU includes shelf life information (3 years), while UltraDrape UGPIV IFU does not; however, expiration dating (2 years) is clearly marked on all levels of UltraDrape UGPIV packaging; therefore, the devices are substantially equivalent. Additionally, the differences in their expiration dating do not impact equivalence, because they have both been tested for safety and performance over their stated shelf life.
• The intended use for the UltraDrape UGPIV includes more specific details on the operator qualifications and device use settings (For use by healthcare professionals appropriately trained in ultrasound within healthcare settings utilizing ultrasound); however, these details are not inconsistent with the specified use of the predicate device.

In conclusion, UltraDrape UGPIV is substantially equivalent to the predicate device Transducer Probe Cover based on the above analysis of the similarities and differences between the devices.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device and the predicate device have the following similarities:

• Both use polyurethane film as a protection mechanism
• Both are available in a sterile format

The proposed device and the predicate device have the following differences:

• UltraDrape UGPIV Barrier and Securement has viral prevention against 20 nm or greater viruses while Transducer Probe Covers has viral prevention against 25 nm or greater viruses. However, this difference is not significant in terms of preventing the transmission of biological risk agents and contaminants, and UltraDrape UGPIV provides protection against even smaller viruses.
• According to the predicate device IFU, it is sometimes distributed with gel; however, UltraDrape UGPIV is not distributed with gel. This does not affect the equivalence of the two devices.
• The Honey probe cover is sterilized via by ETO while UltraDrape UGPIV is sterilized via gamma radiation. This does not affect equivalence because both devices are provided in a sterile format.

Thus, the technological features are substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following test reports were completed for UltraDrape UGPIV Barrier and Securement to determine substantial equivalence to the predicate device, according to the following FDA recognized consensus standards:

-Viral Penetration: ASTM 1671 20 nm Rodent Protoparvovirus PB627-001-V2 (ASTM F1671/F1671-M)
-Tear Resistance: Tear Resistance Result UltraDrape (ASTM D1004)
-Burst Strength: UltraDrape DDL Package Validation Report - Burst Strength (ASTM F1140/F1140M-13)
-Velocity Testing: Acoustic Measurements Report
-Tensile Strength: STA-040 Stability Report Accelerated 2 year 60C Ultradrape (ASTM D5035-11)
-Ultrasound Image Quality and Artifact: "FTR-003 UltraDrape UGPIV Image Clarity and Artifact Report"

UltraDrape® UGPIV has minimal impact on the acoustic output, imaging clarity, and presence of artifact during ultrasound procedures. This has been established by the following testing:
-FTR-003 UltraDrape® UGPIV Image Clarity and Artifact Functional Test confirms does not introduce artifacts and maintains image clarity.
-The Acoustic Measurements Report showed no measurable attenuation at the device's thickness, and that the UltraDrape film does not impact the depth of image penetration or spatial resolution in ultrasound-guided procedures.

UltraDrape UGPIV Barrier and Securement is substantially equivalent to and is as safe, as effective, and performs as well as or better than the predicate device Transducer Probe Covers.