July 1, 2021

K1 Medical LLC
Walt Oko
Manager
56 Newton Road
Woodbridge, Connecticut 06525

Re: K211007
Trade/Device Name: EZ-TRAX™ Persona Knee Containment Device
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 31, 2021
Received: April 2, 2021

Dear Walt Oko:

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,

Clarence W. Murray III -S

Clarence W. Murray, III, PhD
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K211007

Device Name

EZ-TRAX™ Persona Knee Containment Device

Indications for Use *(Describe)*

The **EZ-TRAX™** Persona Knee Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store Persona Knee devices between surgical uses. The **EZ-TRAX™** Persona Knee Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterile barrier system.

Cycle	Temperature	Exposure Time	Drying Time
Dynamic Air Removal	270 F/132 C	4 minutes	10 minutes

Validations included the worst case load configurations of the EZ- TRAX™ Persona Knee Containment Devices.

- Contents in the validated configuration include reusable surgical instruments (impactors, trials, cutting blocks, punches, ankle clamp, etc)
- No lumened devices were validated within the tray system as part of the product load. The EZ-TRAX™ Persona Knee Containment Device does not have any lumen claims.
- Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + Sterile Barrier System + Persona Knee Devices).

The EZ- TRAX™ Persona Knee Containment Device is offered in the following size:

Brand Name	Model	Dimensions
EZ-TRAX™	BASE.ASSY.AL.24.12.2.4	L) 22.97” (W) 11.18” (H) 2.44”

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.

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

K1 Medical LLC's EZ-TRAX Containment Device

K211007

Submitter

K1 Medical LLC
56 Newton Road
Woodbridge, CT 06525

Contact Person: Walt Oko

Phone: 203-913-4161

Date Prepared: March 31, 2021

Name of Device: EZ-TRAX™ Persona Knee Containment Device

Common or Usual Name: Sterilization Cassette

Classification Name: Sterilization Wrap

Regulatory Class: Class II, 21 CFR 880.6850

Product Code: KCT

Predicate Device:

EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device, K1 Medical, K202270

Device Description

The EZ-TRAX™ Persona Knee Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport and store Persona Knee Devices between surgical uses.

The EZ-TRAX™ Persona Knee Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA cleared sterile barrier system.

The subject device protects the interior components during transportation, sterilization, and storage.

The EZ-TRAX™ Persona Knee Containment Device is composed of intrinsically stable metals and thermoplastic polymers. The trays and lids are composed of anodized aluminum with stainless steel handles. The dividers are composed of Aluminum and the posts are composed of medical grade thermoplastic polymers.

The lids and bottom of trays are fully perforated with an evenly distributed hole pattern. The sides of the trays are partially perforated. The trays are used with locking lids.

The trays were designed to be used for sterilization via steam sterilization and used in standard autoclaves found in hospitals and healthcare facilities. The trays were designed in such a way to withstand repeated steam sterilization cycles.

Intended Use / Indications for Use

The **EZ-TRAX™** Persona Knee Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store Persona Knee devices between surgical uses. The **EZ-TRAX™** Persona Knee Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterile barrier system.

Cycle	Temperature	Exposure Time	Drying Time
Dynamic Air Removal	270 F/132 C	4 minutes	10 minutes

Validations included the worst case load configurations of the EZ-TRAX™ Persona Knee Devices.

- Contents in the validation configuration include: reusable surgical instruments (impactors, trials, cutting blocks, punches, ankle clamp, etc).
- No lumended devices were validated within the tray system as part of the product load. The EZ-TRAX™ Persona Knee Containment Device does not have any lumen claims.
- Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + Persona Knee containment devices).

The EZ-TRAX™ Persona Knee Containment Device is offered in the following sizes: .

Brand Name	Model	Dimensions	Weight
EZ-TRAX™	BASE.ASSY.AL.24.12.2.4	(L) 22.97” (W) 11.18” (H) 2.44”	4.25 lbs.

Technological Characteristics Comparison Table
Provided below is a technological comparison of the subject device to the predicate device.

TRADENAME	K1 Medical LLC EZ-TRAX ™ Persona Knee Containment Device K211007	K1 Medical LLC EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device K202270	Comparison
Fundamental Scientific Technology	Sterilization Cassette	Sterilization Cassette	Identical
Product Code	KCT	KCT	Identical
Material Composition	Thermoplastic polymers, Aluminum, and stainless steel	Thermoplastic polymers, Aluminum, and stainless steel	Identical
Design	Base, lid with locking latch and individual inserts	Base, lid with locking latch and individual inserts	Identical
Dimensions	Worst case 24 x 12 x 2.4”	Worst case 24 x 12 x 4”	Identical
Configuration	Perforated bases, lids and inserts	Perforated bases, lids and inserts	Identical
Air Permeance	Yes	Yes	Identical
Percent Perforation	Evenly distributed hole pattern	Evenly distributed hole pattern	Identical
Sterilization Method	Dynamic Air Removal	Dynamic Air Removal	Identical
Sterilization Parameters	Dynamic Air Removal Temperature: 270F Exposure Time: 4 minutes Drying Time: 10 minutes	Dynamic Air Removal Temperature: 270F Exposure Time: 4 minutes Drying Time: 10 minutes	Identical
Reusable	Yes	Yes	Identical
Microbial Barrier Properties	Used with FDA approved sterile barrier system	Used with FDA approved sterile barrier system	Identical
Material Compatibility	Materials compatible with sterilization method	Materials compatible with sterilization method	Identical
Toxicological	Biocompatible	Biocompatible	Identical

Intended Use/ Indications for Use	The EZ-TRAX™ Persona Knee Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store Persona Knee devices between surgical uses. The EZ-TRAX™ Persona Knee Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterile barrier system. Cycle: Dynamic Air Removal Temperature: 270 F/132 C Exposure Time: 4 minutes Drying Time: 10 minutes Validations include the worst case load configurations of the EZ-TRAX™ Persona Knee Devices. - Contents in the validated configuration include: reusable surgical instruments (impactors, trials, cutting blocks, punches, ankle clamp, etc.). - No lumened devices were validated within the tray system as part of the product load. The EZ-TRAX™ Persona Knee Containment Device does not have any lumen claims. -Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + Persona Knee Devices). The EZ-TRAX™ Persona Knee Containment Device is offered in the following size: Brand Name Model Dimensions	The EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store Stryker Mako Total Knee with Triathlon Devices between surgical uses. The EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterile barrier system. Cycle: Dynamic Air Removal Temperature: 270 F/132 C Exposure Time: 4 minutes Drying Time: 10 minutes Sterilization validations included the worst case load configurations of Stryker Mako Total Knee with Triathlon Containment Device utilized the Stryker Mako Total Knee with Triathlon Devices required to perform an arthroplasty procedure. - Contents in the validated configuration include: reusable surgical instruments (impactors, trials, MICS, sagital saws,.arrays, etc.) - No lumened devices were validated within the tray system as part of the product load. The EZ- TRAX™ Stryker Mako Total Knee with Triathlon Containment Device does not have any lumen claims. -Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + Stryker Mako Total Knee with Triathlon Containment Devices).	Same

	EZ-TRAX™ BASE.ASSY.AL.24.12.2.4 (L) 22.97" (W) 11.18" (H) 2.44"	The EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device is offered in the following sizes: Brand Name Model Dimensions EZ-TRAX™BASE.ASSY.AL.24.12.2.4 (L) 22.97" (W) 11.18" (H) 2.44" EZ-TRAX™ BASE.ASSY.AL.21.12.4 (L) 19.97" (W) 11.18" (H) 4.187"	

Summary of Non-Clinical Testing

Provided below is the summary of the non-clinical testing that was performed per specification of the standard and test methodology listed below. The results of the performance testing demonstrated the subject device met the acceptance criteria of the standard and the test methodology.

Non-Clinical Performance Testing Table

Test Methodology	Purpose	Acceptance Criteria	Results
Material Compatibility AAMI TIR12:2010 AAMI ST81:2004/R2016 ISO 17665-1:2006/R2013	To verify the device did not degrade or lose functionality after 25 reprocessing cycles at worst case conditions.	Material compatibility pre-vacuum 132C for 4 minutes – Mechanical Washing and Steam Sterilization The testing subjected the device to repetitive cleaning and sterilization processing for 25 reprocessing cycles at parameters that represented the worst case conditions. Chemical indicators were utilized to demonstrate steam penetration. The study found no degradation or lack of functionality after 25 cycles.	Passed
Mechanical Cleaning Validation – Hemoglobin AAMI TIR30:2011	To verify the manufacturer's cleaning	The mechanical cleaning validation of the EZ-TRAX™ containment system concluded	Passed

ASTM F32018-18 ASTM F3293-18	instructions are effective for removing gross amounts of soil to a hemoglobin level less than 2.2 ug/cm2 per device.	that the manufacturer's cleaning instructions are efficacious for removing gross amounts of soil from the EZ-TRAX™ containment system to a hemoglobin level less than 2.2 µg/cm2 per device. .	
Mechanical Cleaning Validation – Protein Analysis AAMI TIR30:2011 ASTM F32018-18 ASTM F3293-18	To verify the manufacturer's cleaning instructions are effective for removing gross amounts of soil to a protein level of less than 6.4 ug/cm2 per device.	The mechanical cleaning validation of the EZ-TRAX™ containment system protein concluded that the manufacturer's cleaning instructions are efficacious for removing gross amounts of soil from the EZ-TRAX™ containment system to a protein level less than 6.4 µg/cm2 per device.	Passed
MEM Elution Cytotoxicity ISO 10993-5:2009 / R2014	To verify that the device meets requirements of ISO 10993-5 and is not considered cytotoxic.	The cytotoxicity testing was conducted per ISO 10993-5:2009/(R)2014 and concluded that test articles met the requirements of the test and are NOT considered to have a cytotoxic potential.	Passed
Sterilization Validation AAMI ST77:2013 ISO 14937:2009 AAMI ST8:2013	To verify that the device could achieve a sterility assurance level of 10-6 after processing in pre-vacuum steam sterilization cycle of 132F for 4 minutes.	The sterilization validation of the EZ-TRAX™ containment system included pre-vacuum steam 132C for 4 minutes. The conclusion could achieve a Sterility Assurance Level (SAL) of 10-6 after processing in the following pre-vacuum steam sterilization cycle 132C for 4 minutes.	Passed
Thermal Profile Study AAMI ST77:2013	To verify that adequate sterilant penetration can be achieved when processed in pre-vacuum	The thermal profile study of the EZ-TRAX™ Containment Device included pre-vacuum steam 132C for 4 minutes. The study demonstrated that adequate sterilant penetration can be achieved. The EZ-TRAX™	Passed

	steam sterilization cycle of 132C for 4 minutes.	Containment Device can reach and maintain a steady state thermal conditions throughout the exposure phase when processed in the following pre-vacuum steam sterilization cycle 132C for 4 minutes.	
Drying Time Test AAMI ST77:2013 ISO 17665-1:2006/R 2013	To verify that the device is properly dried following processing in pre-vacuum steam sterilization cycle of 132C for 4 minutes and dry time of 10 minutes.	The results demonstrate EZ-TRAX™ meets or exceeds the minimum acceptance criteria for dry time. The EZ-TRAX™ is considered properly dried following processing in the steam pre-vacuum sterilization cycle of 132 C / 270F, Exposure Time 4.0 minutes, and Dry Time 10.0 minimum.	Passed
Handle 100 lbs force test** AAMI ST77:2013	To verify that tray handles did not break or showed evidence of distortion, cracking or other failure following testing with force of 50 lbs.	None of the tray handles broke loose showed evidence of permanent distortion, cracking, or other evidence of failure when tested with force of 50 lbs.	Passed
Sterilization Validation of the Zimmer Persona Total Knee Set with EZ-TRAX™ Cassette (unorganized). AAMI ST8:2013 TIR12:2010 ST77:2013/R2018 ST79:2017 ISO 14937:2009/R2013 ISO 17665-1:2006/R2013	To verify that a Sterility Assurance Level of 10-6 can be achieved after processing in pre-vacuum steam sterilization cycle of 132C for 4 minutes while containing the Zimmer Persona Total Knee Set.	The testing verified that a Sterility Assurance Level of 10^{-6} can be achieved after processing EZ-TRAX™ Persona Knee Containment Device in a steam pre-vacuum cycle at 132C (270F) and 4.0 minutes.	Passed

Conclusions

The conclusions drawn from the nonclinical and clinical tests demonstrate that the EZ-TRAX™ Persona Knee Containment Device is as safe, as effective, and performs as well as or better than the legally marketed device EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device (K202270).