December 23, 2019

K1 Medical LLC
% Joseph Azary
Regulatory Consultant
K1 Medical Technologies
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K192487
Trade/Device Name: EZ-TRAX™ Containment Device
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: November 24, 2019
Received: November 27, 2019

Dear Joseph Azary:

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,

CAPT. Elizabeth Claverie Williams, M.S.
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)*
K192487

Device Name

EZ-TRAX™ Containment Device

Indications for Use *(Describe)*

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

Validated Cycle Times for Dynamic Air Removal Steam Sterilization Cycles

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

Sterilization validations included a worst case EZ-TRAX™ Containment Device and a medical device challenge set comprising of:

- Lumen dimensions (3) 1mm x 500mm
- Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors
- Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws
- A total weight of 42 lbs comprising of (EZ-TRAX™ Containment Device + sterile barrier system + medical device load) as a worst case challenge to the system. Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + medical device load).

The EZ-TRAX™ is offered in the following sizes:

Brand Name	Model	Dimensions
EZ-TRAX™	BASE.ASSY.AL.24.12.2	(L) 22.97" (W) 11.18" (H) 2.04"
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.

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510(K) SUMMARY

K1 Medical LLC's EZ-TRAX™ Containment Device

K192487

Submitter

K1 Medical LLC
56 Newton Road
Woodbridge, CT 06525

Contact Person: Joseph Azary, Regulatory Consultant

Phone: 203-242-6670

Date Prepared: December 21, 2019

Name of Device: EZ-TRAX™ 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: Medtronic Transportation / Sterilization Cassettes (K152241)

Intended Use / Indications for Use

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

Validated Cycle Times for Dynamic Air Removal Steam Sterilization Cycles

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

Sterilization validations included a worst case EZ-TRAX™ Containment Device and a medical device challenge set comprising of:

- Lumen dimensions (3) 1mm x 500mm
- Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors
- Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws
- A total weight of 42 lbs comprising of (EZ-TRAX™ Containment Device + sterile barrier system + medical device load) as a worst case challenge to the system. Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + medical device load).

Device Description

The EZ-TRAX^{TM} Containment Device includes bases with dividers, lids, and brackets fabricated from a variety of materials commonly used to enclose, protect, and organize non-sterile medical devices.

The subject device is not intended to maintain sterility, but it is intended to be used in conjunction with a legally marketed, validated, FDA cleared sterilization wrap.

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

The EZ-TRAX^{TM} 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 bases are fully perforated with an evenly distributed hole pattern. The sides of the bases are partially perforated. The trays are used with locking lids.

The bases / lid assembly was 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.

The following EZ-TRAX^{TM} models / sizes are offered:

Brand Name	**Model**	**Dimensions**
EZ TRAX^{TM}	BASE.ASSY.AL.24.12.2	(L) 22.97” (W) 11.18” (H) 2.04”
EZ TRAX^{TM}	BASE.ASSY.AL.24.12.2.4	(L) 22.97” (W) 11.18” (H) 2.44”

The maximum load is 25 lbs and can be used with different types of medical devices including:

- Devices with lumens up to 500mm in length
- Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors
- Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws

TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE

	Subject Device	**Predicate Device**	**Comparison**
	K1 Medical LLC EZ-TRAX™ Containment Device K192487	**Medtronic Transportation / Sterilization Cassettes K152241**	
Indications for Use	The EZ-TRAX™ Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store medical devices between surgical and other medical uses. The EZ-TRAX™ 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 following parameters and cycles have been validated to attain sterility assurance level (SAL) of 10^{-6}. Cycle Times for Dynamic Air Removal Steam Sterilization Cycles Cycle: Dynamic Air Removal Temperature: 270F / 132C Exposure Time: 4 minutes Drying Time: 10 minutes Sterilization validations included a worst case EZ-TRAX™ Containment Device and a medical device challenge set comprising of: - Lumen dimensions (3) 1mm x 500mm - Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors - Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws - A total weight of 42 lbs comprising of (EZ-TRAX™ Containment Device + sterile barrier	Intended for use in healthcare facilities to organize, enclose, sterilize, transport, and store medical devices and other instrumentation between surgical and other medical uses. The system is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. Sterilization validations included implants and common surgical instruments such as rasps, drivers, trials, handles, inserters, probes, drills, etc. The validated total weight of 28.4 lbs. The validated worst case loading configuration included the following worst case lumen dimensions 363 x 1.575mm and 247.5 x 4.1mm. Cycle: Gravity Displacement Temperature: 250F, 270F, and 275F Exposure Time: 30, 15, and 10 minutes Min Dry Time: 30 minutes Cycle: Dynamic Air Removal Temperature: 270F and 275F Exposure Time: 4 and 3 minutes	Similar

	system + medical device load) as a worst case challenge to the system. Healthcare facilities should not exceed 25 pounds (EZ-TRAX™ Containment Device + sterile barrier system + medical device load).		
Fundamental Scientific Technology	Sterilization Cassette	Sterilization Cassette	Same
Product Code	KCT	*KCT*	Same

Material Composition	Thermoplastic polymers, Aluminum, and stainless steel	Thermoplastic polymers, Aluminum, and stainless steel	Same
Design	Base, lid with locking latch and individual inserts	Base, lid with locking latch and individual inserts	Same
Dimensions	Worst case 24 x 12 x 2.4"	Worst case 22.75 x 11.26 x 5.51"	Similar
Configuration	Perforated bases, lids and inserts	Perforated bases, lids and inserts	
Air Permeance	Yes	Yes	Same
Percent Perforation	Evenly distributed pattern	Evenly distributed hole pattern	Same
Sterilization Method	Dynamic Air Removal	Dynamic Air Removal Gravity Displacement	Similar
Sterilization Parameters	Dynamic Air Removal Temperature: 270F / 132C Exposure Time: 4 minutes Drying Time: 10 minutes	Gravity Displacement 250F, 30 minutes, and 30 minutes dry 270F, 15 minutes, and 30 minutes dry 275F, 10 minutes, and 30 minutes dry Dynamic Air Removal 270F, 4 minutes, and 30 minutes dry 275F, 3 minutes, and 30 minutes dry	Similar
Reusable	Yes	Yes	Same
Microbial Barrier Properties	Used with FDA approved sterile barrier system	Used with FDA approved sterilization wrap	Same
Material Compatibility	Materials compatible with sterilization method	Materials compatible with sterilization method	Same
Toxicological	Biocompatible	Biocompatible	Same

The following technological differences exist between the subject and predicate devices:

- The predicate device has additional processing parameters

Summary of Technological Characteristics

The subject device is composed of anodized aluminum, stainless steel and thermoplastic polymers.
The base and lid is perforated with an evenly distributed pattern and designed to be used for sterilization via steam sterilization. The device is designed in such a way to withstand reported sterilization cycles.

Non-Clinical Performance Data

Cleaning instructions were validated using microbiological, protein, and hemoglobin assays. Sterilization validation, including sterilant penetration and drying time, was performed according to ANSI/AAMI/ISO 17665-1 and 17665-2. Life cycle (simulated usage) testing was performed, which included visual inspection, component dimensional fit verification, and functional closure (lid- bottom latch) verification. Biocompatibility testing was performed using methods described in ANSI/AAMI/ISO 10993-5 (cytotoxicity). No clinical data were included in this submission.

As the EZ-TRAX^{TM} Containment Device has been subjected to performance testing including:

Non-Clinical Performance Testing Table

Test	Standard	Comments	Result
Material Compatibility	AAMI TIR12:2010 AAMI ST79:2017 AAMI ST81:2004/R2016 ISO 17665-1:2006/R2013	Material compatibility pre-vacuum 132C for 4 minutes – Mechanical Washing and Steam Sterilization. The testing subjected the EZ-TRAX™ 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 ASTM F32018-18 ASTM F3293-18	The mechanical cleaning validation of the EZ-TRAX™ concluded 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. .	Passed
Mechanical Cleaning Validation – Protein Analysis	AAMI TIR30:2011 ASTM F32018-18 ASTM F3293-18	The mechanical cleaning validation of the EZ-TRAX™ protein concluded that the manufacturer's cleaning instructions are efficacious for removing gross amounts of soil from the EZ-TRAX™ to a protein level less than 6.4 µg/cm2 per device.	Passed
MEM Elution Cytotoxicity	ISO 10993-5:2009 / R2014	The cytotoxicity testing was conducted per ISO 10993-5:2009/(R)2014 and concluded that EZ-TRAX™ requirements of the test and are NOT considered to have a cytotoxic potential.	Passed

Test	Standard	Comments	Result
Sterilization Validation	AAMI ST77:2013 ISO 14937:2009 AAMI ST8:2013	The sterilization validation of the EZ-TRAX™ 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 AAMI ST79:2017	The thermal profile study of the EZ-TRAX™ included pre-vacuum steam 132C for 4 minutes. The study demonstrated that adequate sterilant penetration can be achieved. The EZ-TRAX™ 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.	Passed
Drying Time Test	AAMI ST77:2013	The study concluded that the EZ-TRAX™ meets or exceeds the minimum acceptance criteria for dry time of 10 minutes.	Passed
Handle 100 lbs force test	AAMI ST77:2013	None of the tray handles broke loose, showed evidence of permanent distortion, cracking or other evidence of failure when tested with a force of 50 lbs on each handle. The study concluded that the EZ-TRAX™ can carry a minimum of four times maximum recommended weight of 25 lbs without deforming, cracking, or exhibiting other evidence of damage.	Passed

Conclusions

The EZ-TRAX™ Containment Device has the same intended use and principles of operation, and very similar indications for use and technological characteristics, as the predicate device. The minor differences between the EZ-TRAX™ Containment Device and the predicate device does not alter its therapeutic purpose or raise new issues of safety or effectiveness, and performance data demonstrate that the EZ-TRAX™ Containment Device is as safe and effective as the predicate device. Thus, the EZ-TRAX™ Containment Device is substantially equivalent to the Medtronic Transportation / Sterilization Cassettes (K152241).

K1 Medical concludes that based on the nonclinical tests performed that the subject device, EZ- TRAX™ Containment Device, is as safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device, Medtronic Transportation / Sterilization Cassettes (K152241), Class II (21 CFR 880.6850), product code KCT.