December 2, 2020

K1 Medical LLC
℅ Joseph Azary
Regulatory Consultant / Application Correspondent
Joseph Azary
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K202270
Trade/Device Name: EZ-TRAX Stryker Mako Total Knee with Triathlon Containment Device
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: October 30, 2020
Received: November 6, 2020

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,

Clarence W. Murray, III, PhD
Acting 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)*

K202270

Device Name

EZ-TRAX™ Stryker Mako Total Knee with Triathlon Containment Device

Indications for Use *(Describe)*

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

Sterilization validations included the worst case load configurations of the EZ- TRAX™ 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).

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”

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.

510(k) SUMMARY

K1 Medical LLC's EZ-TRAX Stryker Mako Total Knee with Triathlon Containment Device

K202270

Submitter

K1 Medical LLC
56 Newton Road
Woodbridge, CT 06525

Contact Person: Joseph Azary, Regulatory Consultant

Phone: 203-242-6670

Date Prepared: November 24, 2020

Name of Device: EZ-TRAX™ Stryker Mako Total Knee with Triathlon 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™ Containment Device, K1 Medical, K192487

Device Description

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.

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

The EZ-TRAX™ Stryker Mako Total Knee with Triathlon 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™** 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	Temperature	Exposure Time	Drying Time
Dynamic Air Removal	270 F/132 C	4 minutes	10 minutes

Sterilization validations included the worst case load configurations of the EZ-TRAX™ 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 validation configuration include: reusable surgical instruments (impactors, trials, MICS, sagittal saws, arrays, etc).

- No lumended 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).

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 Technological Characteristics

Provided below is a comparison of the subject device to the predicate device.

Technological Characteristics Comparison Table

TRADENAME	K1 Medical LLC EZ-TRAX ™ Stryker Mako Total Knee with Triathlon Containment Device K202270	K1 Medical LLC EZ-TRAX™ Containment Device K192487	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 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™ 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: 270F/132C Exposure Time: 4 minutes Drying Time: 10 minutes The validated worst case load configurations of the EZ- TRAX™ Stryker Mako Total Knee with Triathlon Containment Device were utilized. 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”	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. 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	The subject device has specific indications for use with the Stryker Mako Total Knee with Triathlon Containment device. The parameters including cycle, temperature, exposure time, and drying time are identical with no difference. The contents and load configurations of the subject device are different because they are specific to the Stryker Mako Total Knee with Triathlon Containment device.

	- 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.	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.12.12.2 (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”	

Summary of Nonclinical Testing

Provided below is a summary table of the non-clinical testing that were performed using the subject device. The result demonstrated that the subject device nonclinical test results met the acceptance criteria of the standards.

Non-Clinical Performance Testing Table

Test / Methodology	Purpose	Acceptance Criteria	Results
AAMI TIR12:2010 AAMI ST81:2004/R2016 ISO 17665-1:2006/R2013	Material Compatibility	Verify no degradation or lack of functionality after repetitive cleaning and sterilization processing for 25 cycles.	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.
AAMI TIR30:2011 ASTM F32018-18 ASTM F3293-18	Mechanical Cleaning Validation – Hemoglobin	Verify cleaning instructions provided are efficacious for removing gross amounts of soil to a hemoglobin level less than 2.2 ug/cm2 per device.	The mechanical cleaning validation of the EZ-TRAX™ containment system 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.
AAMI TIR30:2011 ASTM F32018-18 ASTM F3293-18	Mechanical Cleaning Validation – Protein Analysis	Verify cleaning instructions provided are efficacious for removing gross amounts of soil to a protein level 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.
ISO 10993-5:2009 / R2014	MEM Elution Cytotoxicity	Verify the device does not have a cytotoxic potential.	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.
AAMI ST77:2013 ISO 14937:2009 AAMI ST8:2013	Sterilization Validation	Verify the device and cycle parameters achieve a Sterility Assurance Level of 10-6.	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.
AAMI ST77:2013	Thermal Profile Study	Verify the device and cycle parameters demonstrate that adequate sterilant penetration is achieved.	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™ 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.

AAMI ST77:2013 ISO 17665-1:2006/R 2013	Drying Time Test	Verify the device is properly dried using the specified cycle parameters.	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.
AAMI ST77:2013	Handle 100 lbs force test	Verify the handles do not show evidence of permanent distortion, cracking, or other evidence of failure when tested with a 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.
AAMI ST8:2013 TIR12:2010 ST77:2013/R2018 ISO 14937:2009/R2013 ISO 17665-1:2006/R2013	Sterilization Validation of the Stryker Mako Triathlon Instrument Set #1 with MICS with EZ-TRAX™	Verify that the device with instrument set specific to device and specified cycle parameters achieve a Sterility Assurance Level of 10-6.	The testing verified that a Sterility Assurance Level of 10^{-6} can be achieved after processing Stryker Mako Triathlon Instrument Set #1 with MICS in a steam pre-vacuum cycle at 132C and 4 minutes.
AAMI ST77:2013 ISO 14937:2009/R2013 ISO 17665-1:2006/R2013	Sterilization validation of Stryker Mako Triathlon Universal TKA with EZ-TRAX™	Verify that the device with implants specific to device and specified cycle parameters achieve a Sterility Assurance Level of 10-6.	The testing verified that a Sterility Assurance Level of 10^{-6} can be achieved after processing Stryker Mako Triathlon Universal TKA01 and TKA03 in a steam pre-vacuum cycle at 132C and 4 minutes.

Conclusions

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