December 30, 2020

CrossRoads Extremity Systems, LLC
Kim Strohkirch
Sr. Director, QA/RA/Compliance
6055 Primacy Pkwy, Suite 140
Memphis, Tennessee 38119

Re: K202268
Trade/Device Name: CrossRoads Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 1, 2020
Received: December 2, 2020

Dear Kim Strohkirch:

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,

For Clarence W. Murray, III, Ph.D.
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)*
K202268

Device Name
CrossRoads Tray System

Indications for Use *(Describe)*
The CrossRoads Tray System is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The CrossRoads Tray System are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case CrossRoads Tray System included surgical instruments such as drills, inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Tray System were validated for a maximum load of 8.5 lbs (tray + instruments).

Method:	Steam Sterilization (Moist Heat Sterilization) Cycle Prevacuum
Temperature:	270 ˚F (132 ˚C)
Exposure time:	4 minutes
Drying time:	20 minutes

The tray is 20.60” length x 9.80” width x 2.00” depth.

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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“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
K202268

Date:	December 27, 2020
Device Name:	*CrossRoads Tray System*
Establishment Registration:	3011421599
Company:	CrossRoads Extremity Systems 6055 Primacy Parkway, Suite 140 Memphis, TN 38119 USA
Contact Person:	Kim Strohkirch Sr. Director, QA/RA/Compliance CrossRoads Extremity Systems 901.221.8406 kstrohkirch@crextremity.com
Trade Name:	*CrossRoads Tray System*
Common Name:	Sterilization Tray
Classification:	Class II
Regulation Number:	21 CFR 880.6850 Sterilization Wrap Containers, Trays, Cassettes & other Accessories
Panel:	General Hospital
Product Code:	KCT
Predicate Devices:	K200632 TCAT TKA Instrument Tray Set
Device Description:	The subject *CrossRoads Tray System* is a reusable sterilization tray or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit which contains and protects the interior components during sterilization. All components are perforated for steam penetration. The tray can hold implants and instruments such as inserters, K-wire guides, fixation pins, reamers and ratcheting handles. The tray is 20.60” length x 9.80” width x 2.00” depth.

Indications for Use:

The *CrossRoads Tray System* is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The CrossRoads Tray System are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case CrossRoads Tray System included surgical instruments such as drills, inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Tray System were validated for a maximum load of 8.5 lbs (tray + instruments).

Method	Steam Sterilization (Moist Heat Sterilization)
Cycle	Prevacuum
Temperature	270 ˚F (132 ˚C)
Exposure time	4 minutes
Drying time	20 minutes

The tray is 20.60” length x 9.80” width x 2.00” depth.

Materials:

The *CrossRoads Tray System* tray is manufactured from aluminum conforming to ASTM B029, silicone, 304 stainless steel conforming to ASTM A240 and ASTM A313, 18-8 stainless steel, 17-4 stainless steel 304 stainless steel, and 316 stainless steel.

Technology Characteristics:

Shown below is a Technological Characteristics Comparison Table that compares the subject device and the predicate device in this submission:

	Subject Device	Predicate Device	Comparison
510(k)	K202268	K200632	Different
Name	CrossRoads Tray System	THINK Surgical TCAT TKA Instrument	Different
Product Code	KCT	KCT	Same
Intended Use	The *CrossRoads Tray System* is designed to hold various surgical instruments in order to organize, steam sterilize, and transport the instruments between uses. The trays are wrapped with an FDA- cleared sterilization wrap during the pre- vacuum autoclave sterilization process.	The THINK Surgical TCAT® TKA Instrument Tray Set is intended to protect, organize and deliver to the surgical field TCAT® tools, instruments and accessories. The trays allow sterilization of tools, instruments and accessories, and maintain sterility of the enclosed devices until used. The trays are wrapped with an FDA-cleared sterilization wrap during the pre-vacuum autoclave sterilization process.	Similar
Intended Instrument Tray Set Content Maximum Load	Medical devices/ instruments weighing no more than 8.5 lbs (tray + instruments).	Medical devices/ instruments weighing no less than 7.5lbs-18.0lbs. total including the weight of the trays.	Different
Material	Lid/base/Lift out tray – Aluminum Inserts – Silicone, aluminum, stainless steel Latch – Stainless steel	Lid/base/Lift out tray – Aluminum Inserts – Silicone, aluminum, stainless steel, nylon Latch – Stainless steel	Similar
Design	Base and lid	Base, lift out tray, lid	Similar
Insert	Yes	Yes	Same
Dimensions	20.60 length x 9.80 width x 2.00 inches depth	20 length x 9.8 width x 4.5 inches depth	Similar
Sterilization			
Sterilization Method	Pre-vacuum (Steam)	Pre-vacuum (Steam)	Same
Cycle Temperature	270 ˚F (132 ˚C)	270 ˚F (132 ˚C)	Same
Cycle Time	4 minutes	4 minutes	Same
Drying Time	20 minutes	45 minutes	Different
Non-Clinical Performance Test	• Sterilization Efficacy • Cleaning • Biocompatibility	• Sterilization Efficacy • Packaging • Cleaning • Biocompatibility • Use and Sterile Processing Guide	Similar

Performance Testing:

Name of Testing	Purpose of Testing	Acceptance Criteria	Results
ER20-0010 Sterilization Efficacy (ANSI/AAMI/ISO 14937:2013 – Sterilization of Healthcare Product – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices)	To verify the *CrossRoads Tray System* containing the maximum load were inoculated with biological indicators placed in areas of the trays deemed to be most difficult for sterilant (steam) to penetrate. Following inoculation, the trays were wrapped in FDA-cleared sterilization wraps. The trays indicated that the biological indicators (BI) Overkill method provided a six-log reduction of the indicator organism.	No growth on half cycles. No moisture on full drying cycle.	In the three pre-vacuum autoclave cycles, 2 minutes at 270°F was sufficient to sterilize the BI's in the DynaBunion Non-Sterile Set, 15NS-4800, when seeded with (8) BI carriers impregnated with *Geobacillus stearothermophilus* and (2) SporView self-contained BI's. Since this is a half-cycle validation, the 4-minute full cycle exposure time will provide the required Sterility Assurance Level (SAL) of 10-6. Positive controls showed growth for all three cycles. Negative controls remained negative (no growth) for all three cycles. There was no evidence of moisture on or within the sterilized package, wrap, and instruments. There was no recorded weight gain after each of the pre-vacuum sterilization cycles.
20-0963 CREX Reprocessing (AAMI TIR12-2010 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers and AAMI TIR30-2011 A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices)	To verify the instruments in the *CrossRoads Tray System* for cleanability according to the user instructions.	Meets the AAMI TIR-30 guideline acceptance criteria of ≤ 6.4µg/cm^2 protein residuals and ≤ 2.2µg/cm^2 for hemoglobin residuals.	Three (3) cleaning cycles were performed on 5 instruments and meet the acceptance criteria.
20-2723 CREX (AAMI TIR12-2010 Designing, testing and labeling reusable	To verify the *CrossRoads Tray System* for cleanability according to the user	Meets the AAMI TIR-30 guideline acceptance criteria of ≤ 6.4µg/cm^2 protein	Three (3) cleaning cycles were performed on the tray and meet the acceptance criteria.

Name of Testing	Purpose of Testing	Acceptance Criteria	Results
medical devices for reprocessing in health care facilities: A guide for medical device manufacturers and AAMI TIR30-2011 A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices)	instructions	residuals and ≤ 2.2µg/cm^2 for hemoglobin residuals.	
ER20-0010 Biocompatibility (ANSI/AAMI/ISO 10993-5:2009 - Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity)	To verify the *CrossRoads Tray System* were evaluated for biocompatibility according to ISO 10993-1. The results indicated biocompatibility requirements were met.	Pass is a score of less than 2.	There was no cytotoxic reaction observed (Grade 0) on the ratchet handle, for any of the sample extracts at 24 and 48hrs contact. Positive controls were positive (Grade 4) at 24 and 48hrs.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.