July 16, 2024

CrossRoads Extremity Systems
Jacqueline Gorberg
Regulatory Affairs Specialist II
6423 Shelby View Dr., Suite 101
Memphis, Tennessee 38134

Re: K241050
Trade/Device Name: CrossRoads Modular Tray System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 17, 2024
Received: April 17, 2024

Dear Jacqueline Gorberg:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.07.16 17:47:19 -04'00'

for: Christopher K. Dugard, MS
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241050

Device Name
CrossRoads Modular Tray System

Indications for Use *(Describe)*

The CrossRoads Modular Tray System is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during sterilization and during implant/prosthetic treatment. The CrossRoads Modular Tray 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 for the worst-case CrossRoads Modular Tray System included surgical instruments such as inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Modular Tray System is validated for a maximum load of 18.7 lbs (tray + instruments).

Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum
Temperature: 270 °F (132 °C)
Exposure time: 4 minutes
Drying time: 20 minutes

Dimensions do not exceed:
20.546" length x 10.022" width x 3.978" 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 – K241050

Applicant Name: CrossRoads Extremity Systems

Applicant Address: 6423 Shelby View Dr., Suite 101 Memphis TN 38134 United States

Applicant Contact Telephone: (267) 885-9690

Applicant Contact: Ms. Jacqueline Gorberg

Applicant Contact Email: jgorberg@its.jnj.com

Prepared On Date: July 15, 2024

Device Name

Device Trade Name: CrossRoads Modular Tray System

Common Name: Sterilization Wrap

Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Regulation Number: 21 CFR 880.6850

Product Code: KCT

Legally Marketed Predicate Device

Predicate #: K202268

Predicate Trade Name: CrossRoads Tray System

Product Code: KCT

Device Description Summary

The CrossRoads Modular Tray System is a reusable sterilization case with organizing trays 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 instruments during sterilization. All components are perforated for steam penetration. The tray can hold CrossRoads surgical instruments.

Indications for Use

The CrossRoads Modular Tray System is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during sterilization and during implant/prosthetic treatment. The CrossRoads Modular Tray 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 for the worst-case CrossRoads Modular Tray System included surgical instruments such as inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Modular Tray System is validated for a maximum load of 18.7 lbs. (tray + instruments).

Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum

Temperature: 270 °F (132 °C)

Exposure time: 4 minutes

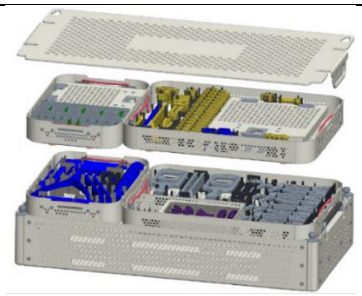
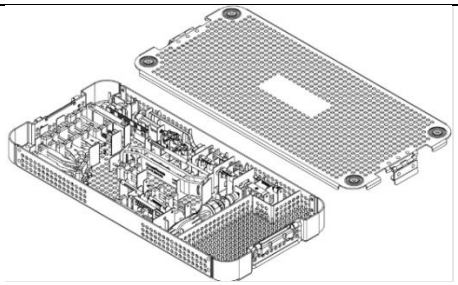
Drying time: 20 minutes

Dimensions do not exceed:

20.546" length x 10.022" width x 3.978" depth

Technological Comparison

The subject CrossRoads Modular Tray System is identical to the predicate CrossRoads Tray System (K202268) in terms of basic design, fundamental technology, and manufacturing and sterilization methods. Differences include a change to maximum load, size, system features, and cleaning methods.

Comparator	Comparison (subject vs predicate device)	Subject Device (K241050)	Predicate Device (K202268)
Device Name	Different, name change	CrossRoads Modular Tray System	CrossRoads Tray System
Device Image	Different, new tray design		
Product Code	Same	KCT	KCT
Intended Use	Similar, name change only	The CrossRoads Modular 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 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.
Indications for Use	Different, updated name, weight, and dimensions	The CrossRoads Modular Tray System is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during sterilization and during implant/prosthetic treatment. The CrossRoads Modular Tray System is not intended on its own to maintain sterility; it	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

<table>
<tr><td></td><td></td><td>is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. Sterilization validations for the worst-case CrossRoads Modular Tray System included surgical instruments such as inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Modular Tray System is validated for a maximum load of 18.7 lbs (tray + instruments).
Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum
Temperature: 270 °F (132 °C)
Exposure time: 4 minutes
Drying time: 20 minutes

Dimensions do not exceed:
20.546” length x 10.022” width x 3.978” depth</td><td>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 is validated for a maximum load of 8.5 lbs (tray + instruments).
Method: Steam Sterilization (Moist Heat Sterilization) Cycle Pre-vacuum
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.</td></tr>
<tr><td>System Features</td><td>Different, design change to include lift out trays</td><td>Basic lid/base design
Inserts
Perforated
Handles
Latches
Lift out trays</td><td>Basic lid/base design
Inserts
Perforated
Handles
Latches</td></tr>
<tr><td>Material</td><td>Different, new materials included</td><td>Lid/base– Aluminum
Inserts – Silicone, Aluminum, Stainless Steel, Nylon-coating
Latch – Stainless Steel
Lift out trays – Aluminum, Stainless Steel, PROPYLUX, Radel</td><td>Lid/base – Aluminum
Inserts – Silicone, Aluminum, Stainless Steel, Nylon-coating
Latch – Stainless Steel</td></tr>
<tr><td>Dimensions (inches)</td><td>Different, change to dimensions</td><td><table><tr><th>Part Number</th><th>Dimensions</th></tr><tr><td>2806OCPKG</td><td>20.08” length x 9.84” width x 3.978” depth</td></tr><tr><td>28061LPKG</td><td>9.824” length x 6.594” width x 0.716” depth</td></tr><tr><td>28062LPKG</td><td>13.260” length x 9.626” width x 0.749” depth</td></tr></table></td><td>20.60” length x 9.80” width x 2.00” depth</td></tr>
</table>

		2806PIPKG	9.213” length x 6.299” width x 1.772” depth	
		2806SIPKG	12.756” length x 9.213” width x 1.772” depth	
		28061EPKG	9.213” length x 6.299” width x 1.772” depth	
		28062EPKG	12.756” length x 9.213” width x 1.772” depth	
		2806DBPKG	12.756” length x 9.213” width x 1.772” depth	
		2806MPPKG	9.213” length x 6.299” width x 1.772” depth	
		2806KLPKG	4.862” length x 2.832” width x 1.225” depth	
		2806OLPKG	20.546” length x 10.022” width x 1.5” depth	
System Content	Similar, predicate already included instruments as system content	Instruments		Implants and instruments
Intended Maximum Load	Different, updated system load	Tray + system content weighing no more than 18.7 lbs		Tray + system content weighing no more than 8.5 lbs
Sterilization Parameters	Same	Sterilization method: Pre-vacuum (steam) Cycle Temperature: 270°F (132°C) Cycle Time: 4 minutes Drying Time: 20 minutes		Sterilization method: Pre-vacuum (steam) Cycle Temperature: 270°F (132°C) Cycle Time: 4 minutes Drying Time: 20 minutes
Sterile Barrier	Similar, predicate already included FDA cleared sterilization	FDA cleared sterilization wrap		FDA cleared sterilization wrap or pouch

	wrap as the sterile barrier		
Cleaning Methods	Different, change to cleaning methods	1. **Disassemble** all components as per manufacturer instructions (if appropriate). Open all hinged instruments.* **2. Rinse*** 3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 10 minutes.* 4. **Scrub*** 5. **Rinse** with cold tap water for a minimum of two minutes; use a syringe to repeatedly flush any very narrow lumens.* 6. **Rinse*** 7. **Sonicate** for a minimum of 15 minutes in an enzymatic detergent solution prepared per manufacturer directions.* 8. **Rinse** thoroughly /flush with RO/DI water for a minimum of two minutes.* 9. **Dry*** 10. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean. Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.* *Cleaning methods are the same to those of the reference device NOTE: Steps have been truncated if there is no difference in cleaning method to that of the predicate device (i.e. Steps 2, 4, 6, and 9)	1. **Disassemble** all components as per manufacturer instructions (if appropriate). 2. **Rinse** 3. **Bathe** in an enzymatic detergent solution prepared per manufacturer instructions for 5 minutes. 4. **Scrub** 5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens. 6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes. 7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe. 8. **Rinse** 9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions. 10. **Rinse** thoroughly/flush with RO/DI water. 11. **Dry** 12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean. NOTE: Steps 2, 4, 8, and 11 are comparable to the subject device; thus, steps have been truncated.
Non-clinical Data	Same	• Sterilization Efficacy • Cleaning • Biocompatibility • Handle Strength Assessment	• Sterilization Efficacy • Cleaning • Biocompatibility • Tolerance and handle strength analysis

Non-Clinical and/or Clinical Tests Summary

Nonclinical testing included Sterilization Efficacy, Cleaning Validation, Biocompatibility, and Handle Strength Assessment. The data was used for the determination of substantial equivalence. Testing demonstrates that the CrossRoads Modular Tray System is as safe and effective as its predicate device.

Test	Standard / Method	Acceptance Criteria	Results
Sterilization Efficacy	ISO 17665-1:2006(R)20013 ISO11138-1:2017 AAMI ST79:2017 AAMI TIR12:2020	Sterilization Validation: All BI's processed in each half-cycle must be negative for microbial growth of the indicator organism after 7 days for the overkill method to be validated. Positive controls must show growth of the indicator organism. Negative controls must remain negative (no growth). Dry Time Validation: The dry time validation is successful if the weight differential of the wrapped case after sterilization does not increase by 0.2% of the pre-sterilization weight, and there is no evidence of moisture on or within the sterilized package, wrap, and instruments.	Pass
Cleaning Validation	AAMI TIR30:2011 ISO19227 AAMI TIR12:2020 AAMI ST98:2022 ASTM F2459 (2018) ASTM D4839-03 (2017)	Acceptance Criteria 1: Visual Inspection - Visibly clean without evidence of discoloration, residue or particulate to the unaided eye without magnification under normal task lighting.	Pass

		Acceptance Criteria 2: Protein ≤ 6.4 µg/cm2 Acceptance Criteria 3: Hemoglobin ≤ 2.2 µg/cm2 Acceptance Criteria 4: TOC ≤1000 mg/device (or 100 mg/cm2 for devices larger than 50cm2)	
Biocompatibility	ISO 10993-1:2018	The materials are biocompatible	Pass
Handle Strength Assessment	Shear and Tensile Strength Analysis - 501913762	The lowest failure force determined in the assessment of handle assembly components must be greater than the maximum load of 18.7lbs.	Pass

Clinical testing was not necessary for the determination of substantial equivalence.

Conclusions

The conclusions drawn from the nonclinical tests demonstrates that the subject device, K241050, CrossRoads Modular Tray System, is as safe, as effective, and performs as well as or better than the legally marketed device, cleared under K202268.