March 19, 2020

TDM Co. Ltd.
℅ Dave Kim
Medical Device Regulatory Affairs
Dave Kim
1830 Buffalo Speedway
Houston, Texas 77025

Re: K191057
Trade/Device Name: Park's Pectus System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 10, 2019
Received: April 22, 2019

Dear Dave Kim:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K191057

Device Name
Park's Pectus System

Indications for Use *(Describe)*

Park’s Pectus System is intended for use in surgical procedures to repair Pectus Excavatum and other anterior chest wall deformities

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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510(k) Summary
K191057

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: 2/17/2020

1. 510K Applicant / Submitter:

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2. Submission Contact Person

Dave Kim, MBA
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Email: davekim@mtech-inc.net

3. Device

-. Trade / Device Name : Park's Pectus System
-. Common Name : Pectus Excavatum System
-. Classification Name : Plate, Fixation, Bone
-. Regulation Number : 21 CFR 888.3030
-. Regulation Name : Single/multiple component metallic bone fixation appliances and accessories
-. Regulatory Class : II
-. Product Code : HRS

4. Primary predicate Device

-. Trade / Device Name : Lorenz Pectus Support Bar System
-. 510(k) Number : K061384
-. Regulation Number : 21 CFR 888.3030
-. Regulation Name : Single/multiple component metallic bone fixation appliances and accessories
-. Regulatory Class : II
-. Product Code : HRS

5. Reference Device

5.1 Reference Device #01

-. Trade / Device Name : TDM Plate and Screw System
-. 510(k) Number : K171808
-. Regulation Number : 21 CFR 888.3030

-. Regulation Name : Single/multiple component metallic bone fixation appliances and accessories
-. Regulatory Class : II
-. Product Code : HRS, HWC

5.2 Reference Device #02

-. Trade / Device Name : TDM Plate and Screw System
-. 510(k) Number : K190391
-. Regulation Number : 21 CFR 888.3030
-. Regulation Name : Single/multiple component metallic bone fixation appliances and accessories
-. Regulatory Class : II
-. Product Code : HRS, HWC

6. Description:

Park's Pectus System is used in a minimally invasive surgical procedure to correct pectus excavatum, a type of deformity of the thoracic wall, characterized by a concave shaped chest. This device consists of pectus bar and stabilizer to lift the sternum upwards to lessen the severity of the deformity.
Park's Pectus System includes appliance accessories used in surgical procedures to insert a fixation bar into the thoracic cavity and get it fixed to the coastal ribs for repairing pectus excavatum, a type of deformity of the thoracic wall.

7. Indications for Use

Park's Pectus System is intended for use in surgical procedures to repair Pectus Excavatum and other anterior chest wall deformities.

8. Substantial Equivalence Discussion:

The Park's Pectus System is substantially equivalent to Lorenz Pectus Support Bar System (K061384). The following comparison table is presented to demonstrate substantial equivalence.

	Candidate Device	**Primary predicate**	**Substantial Equivalence Analysis**
510(k) Number	K191057	K061384	-
Device Name	Park's Pectus System	Lorenz Pectus Support Bar System	-
Common Name	Single/multiple component metallic bone fixation appliances and accessories	Single/multiple component metallic bone fixation appliances and accessories	-
Manufacturer	TDM CO., LTD. (Korea)	Biomet Microfixation Inc. (USA)	-
Indication for Use	Park's Pectus System is intended for use in surgical procedures to repair Pectus Excavatum and other anterior chest wall deformities.	This device is intended for use in surgical procedures to repair Pectus Excavatum and other chest wall deformities.	Substantial Equivalence
Indication	Congenital deformity of the sternum and anterior chest wall	Congenital deformity of the sternum and anterior chest wall	Substantial Equivalence
Contraindication	- Patients with mental or neurological conditions who are unwilling or incapable of following instructions. - Patients presenting metal sensitivity reactions.	- Patients with mental or neurological conditions who are unwilling or incapable of following instructions. - Patients presenting metal sensitivity reactions.	Substantial Equivalence

	- Patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling. - Infection	- Patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling. - Infection	
Raw Material	Titanium Alloy (ASTM F136) Stainless Steel (ASTM F138 & ASTM F139)	Titanium Alloy (ASTM F136) Stainless Steel (ASTM F138)	Substantial Equivalence
Feature	- The Pectus Bar's rounded ends and blunt edges help minimize tissue destruction during implant insertion. The Pectus Bar comes in a variety of lengths ranging from 6 inches to 17 inches to accommodate most Pectus Excavatum correction procedures - All instruments in the Pectus System are designed to increase simplicity during the Nuss Procedure. - The Pectus System Container comes in two sizes and conveniently houses the entire range of Pectus implants and instruments - Specialized titanium bars and stabilizers available for patients with nickel allergies - Pectus-size bars available for the following: ① Special sized bars ② Pre-bent bars developed in accordance with patients' CT scans	- The Pectus Bar's rounded ends and blunt edges help minimize tissue destruction during implant insertion. - The Pectus Bar comes in a variety of lengths ranging from 7 inches to 17 inches to accommodate most Pectus Excavatum correction procedures. - All instruments in the Pectus System are designed to increase simplicity during the Nuss Procedure. - The Pectus System Container comes in two sizes and conveniently houses the entire range of Pectus implants and instruments - Specialized titanium bars and stabilizers available for patients with nickel allergies - Pectus-size bars available for the following: ① Special sized bars ② Pre-bent bars developed in accordance with patients' CT scans	Substantial Equivalence
Surgical Procedure	MIRPE (Minimally Invasive Repair of Pectus Excavatum)	MIRPE (Minimally Invasive Repair of Pectus Excavatum)	Substantial Equivalence
Pectus Bar Length	6 inch ~ 17 inch	7 inch ~ 17 inch	Substantial Equivalence
Single use	Yes	Yes	Substantial Equivalence
Non-Sterile Packaging	Yes	Yes	Substantial Equivalence
Target Population	Patients with congenital deformity of the sternum and anterior chest wall	Patients with congenital deformity of the sternum and anterior chest wall	Substantial Equivalence
Anatomical Site	Sternum and anterior chest wall	Sternum and anterior chest wall	Substantial Equivalence
Location of Use	Use only by professional orthopedists	Use only by professional orthopedists	Substantial Equivalence
Bio-compatibility	All user directly contacting materials are compliance with ISO10993 requirements.	All user directly contacting materials are compliance with ISO10993 requirements.	Substantial Equivalence

Park's Pectus System and the primary predicate device[Lorenz Pectus Support Bar System (K061384)] have identical indication for use statements and the same intended use.

The device specifications and materials are equal to the primary predicate device[Lorenz Pectus Support Bar System (K061384)] in all parameters.

The materials and sterilization method for Parks Pectus System including class I and class II accessories are identical to TDM plate and screw systems cleared by FDA (K190391)

Therefore, the Park's Pectus System is substantially equivalent to the primary predicate device[Lorenz Pectus Support Bar System (K061384)].

9. Performance Tests (Non-clinical)

Non-clinical performance tests, including 4-point bending test, 4-point bending fatigue test, vertical tensile test, were performed by comparing Park's pectus system with Lorenz pectus support bar system (K061384). The selection rationale of the test sample was based on the worst case scenario, a pectus bar with the longest and thinnest in size. All Park's pectus bar has the same width. The size of Park's pectus bars tested are 431.8 mm (17 inch) long x 12.7mm width x 2.8 mm thick. For material, both stainless and titanium pectus bars were tested. Pectus bars with both rounded end and serrated end were also tested. Other accessories (fixator driver, applier, bar removal bender, clamp, flipper, table top bender, easy crane system, flare compressor, and fixator container) were not considered in this test since there have been well established safety and effectiveness history for class I stainless and titanium surgical instruments.

-. ASTM F382-14 Standard Specification and Test Method for Metallic Bone Plates

10. Biocompatibility Tests

The materials for Parks Pectus System including class I and class II accessories are identical to TDM plate and screw systems (K171808/K190391) cleared by FDA.

ASTM F138 & ASTM F139 stainless steel, the same materials used for Park's Pectus Bar System, have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

"The [Titanium Alloy(ASTM F136)] of Park's Pectus Bar in its final finished form is identical to the [Titanium Alloy(ASTM F136)] of the [TDM Plate And Screw System (K171808/ K190391) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)."

" Park's Pectus Bar in its final finished form is identical to [TDM Plate And Screw System (K171808/K190391) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)."

11. Summary of Clinical Tests

Clinical testing was not required to demonstrate the substantial equivalence of the Park's Pectus System to its primary predicate device.

12. Conclusions:

Based on the information provided in this premarket notification, TDM CO., LTD. concludes that the Park's Pectus System is substantially equivalent to the primary predicate as described herein.