October 27, 2022

CurvaFix, Inc.
% Lisa Pritchard
Vice President, Regulatory, Quality, Clinical & Engineering
Duval & Associates, P.A.
825 Nicollet Mall
Medical Arts Building Suite 1820
Minneapolis, Minnesota 55402

Re: K222505
Trade/Device Name: CurvaFix IM System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 18, 2022
Received: August 18, 2022

Dear Lisa Pritchard:

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, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222505

Device Name
CurvaFix® IM System

Indications for Use *(Describe)*
The CurvaFix® IM System is intended for fixation of fractures of the pelvis.

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

510(k) Owner: CurvaFix, Inc.
1406 Place NE
Suite 107
Bellevue, WA 98007
Contact: Steve Dimmer
Phone: 425.276.8800
Date prepared: October 27, 2022

Device Name: Trade Name: CurvaFix IM System
Common Name: Threaded Metallic Bone Fixation Fastener
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulation: 21 CFR §888.3040
Regulatory Classification: 2
Product Code: HWC

Predicate Devices: **Primary:** CurvaFix Intramedullary Rodscrew System (K180050)
Additional: Synthes 3.5mm Cortex Screw (K043185)

Device Description:
The CurvaFix IM System is a collection of flexible intramedullary devices for pelvic fracture fixation. The devices have a threaded, self-tapping distal end and a driving torque interface at the proximal end. An integral shape lock feature changes the IM Implant from a flexible to rigid state after implantation. The IM Implant can be returned to a flexible state should device explant be required. The implants are available in two diameters (7.5mm and 9.5mm) and lengths ranging from 90mm to 180mm to accommodate a variety of anatomic requirements.

Indications for Use
The CurvaFix® IM System is intended for fixation of fractures of the pelvis.

Substantial Equivalence Comparison with the Predicate Devices
Indications for Use are identical to the primary predicate device with the exception of the rebranded product name. The product name has been changed from CurvaFix Intramedullary Rodscrew System to CurvaFix IM System. No other changes have been made to the Indications for Use. This is a minor change with no impact on the use of the device, so does not constitute a new intended use.

The subject CurvaFix IM System and the selected predicate devices both have the same intended use for providing fracture fixation. The CurvaFix IM System also has the same Indications for Use, type of use, anatomic location, mechanism of action, and method of stabilization as both the primary and additional

predicate devices. The CurvaFix IM System also has the same material, basic design, and cutting flutes as the primary predicate device. Where there are differences between the CurvaFix IM System and the predicate devices, those differences do not raise new questions of safety of effectiveness. The differences between the CurvaFix IM System and the primary predicate device include major diameter, length range, minor diameter, attachment of the distal end, cable pathway, cable design, bead shape and orientation, and minor instrument modifications. All of these differences have been determined to not raise different questions of safety and effectiveness in comparison to the predicate devices. The verification and validation data demonstrate that the CurvaFix IM System functions as intended. Therefore, the criteria for a substantial equivalence determination have been met.

Non-Clinical Performance Data

Mechanical testing of worst-case CurvaFix IM Implants was performed according to ASTM F543-17. Additional mechanical properties were evaluated following ASTM F1264-16e1: 2016. Testing included driving torque, pullout strength, torsional properties, static four-point bend, and bending fatigue. A simulated use study was also conducted in a cadaver model, validating updates to the instruments. The mechanical test results and simulated use study demonstrate that performance of the CurvaFix IM Implant is substantially equivalent to the primary predicate device.

Conclusion

The worst-case configuration of CurvaFix IM Implant met all established acceptance criteria for mechanical testing that were based upon performance of the primary predicate device. This demonstrates that the device function is as safe, as effective, and performs as well as the primary predicate device. The data provided supports substantial equivalence of the CurvaFix IM System to the predicate devices.