August 29, 2025

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

Re: K252019
Trade/Device Name: CurvaFix Low Profile System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: June 27, 2025
Received: June 30, 2025

Dear Ms. 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252019

Please provide the device trade name(s).

CurvaFix Low Profile System;

Please provide your Indications for Use below.

The CurvaFix® Low Profile System is intended for fixation of fractures of the pelvis.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K252019

510(k) Summary

510(k) Owner:

CurvaFix, Inc.
1406 140th Place NE
Suite 107
Bellevue, WA 98007
Contact: Mark Foster
Phone: 425.276.8800
Date prepared: August 21, 2025

Device Name:

Trade Name: CurvaFix Low Profile System
Common Name: Threaded Metallic Bone Fixation Fastener
Classification Name: Smooth or threaded metallic bone fixation fastener, and single/multiple component metallic bone fixation appliances and accessories
Regulation: 21 CFR §888.3040, and 21 CFR §888.3030
Regulatory Classification: 2
Product Code: HWC, HTN

Predicate Devices:

Primary: CurvaFix IM System (K222505)
Additional: CurvaFix Intramedullary Rodscrew System (K180050)
Additional: Smith & Nephew Cannulated Screws & Washers (K213126)

Device Description:

The CurvaFix Low Profile 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 CurvaFix Implant from a flexible to rigid state after implantation. The CurvaFix 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 210mm to accommodate a variety of anatomic requirements. Two Washers are available for distribution of load in poor bone. The CurvaFix Low Profile Implant is placed using several Class II device-specific instruments and additional Class I accessories.

Indications for Use

The CurvaFix® Low Profile 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 IM System to CurvaFix Low Profile 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 Low Profile System and the selected predicate devices all have the same intended use for providing fracture fixation. The CurvaFix Low Profile System also has the same Indications for Use, type of use, anatomic location, material, mechanism of action, and method of stabilization as both the primary and additional predicate devices. The CurvaFix Low Profile System also has the same basic design, minor diameter, and major diameter as the primary predicate device. Where there are differences between the CurvaFix Low Profile System and the predicate devices, those differences do not raise different questions of safety of effectiveness. The differences between the CurvaFix Low Profile System and the primary predicate device include length range, proximal head/housing, washers, and instruments. All 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 Low Profile 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 Low Profile Implants was performed according to ASTM F543-23. Additional mechanical properties were evaluated following ASTM F1264-16e1: 2024. Testing included driving torque, pullout load, torsional properties, static four-point bend, bending fatigue, integrity after shipping, implant radius of curvature, implant torque to lock and unlock, implant cable tensile, and washer pull through. Testing was also conducted to verify updates to the instruments. The test results demonstrate that performance of the CurvaFix Low Profile Implant is substantially equivalent to the primary predicate device.

Conclusion

The worst-case configuration of CurvaFix Low Profile Implant and instruments met all established acceptance criteria for testing required for 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 Low Profile System to the predicate devices.