November 26, 2024

FootBridge Medical
% Michael Coladonato
Associate Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K241995
Trade/Device Name: HyperFlex™ Bunion Correction 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, HWC
Dated: October 28, 2024
Received: November 1, 2024

Dear Mr. Coladonato:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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)*
K241995

Device Name
HyperFlex™ Bunion Correction System

Indications for Use *(Describe)*
The FootBridge Medical HyperFlex™ Bunion Correction System is intended for use in reconstruction (correction) of the hallux valgus deformity by holding the reduction of the 1st metatarsal-2nd metatarsal intermetatarsal (IM) angle in adults and pediatric patients aged ≥13 years in which growth plates have fused.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Device Trade Name: HyperFlex™ Bunion Correction System

Manufacturer: FootBridge Medical, LLC
520 Elliot Street
Charlotte, NC 28202
(704) 843-7852

Official Correspondent: Michael Coladonato
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Prepared by: MCRA, LLC
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Office: 202.552.5800

Date Prepared: November 26, 2024

Classifications: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener.

Common Name: Bunion Correction System

Class: II

Product Codes: HRS, HWC

Primary Predicate: Arthrex Mini TightRope and the Mini TightRope FT (Arthrex, K090107)

Indications For Use:
The FootBridge Medical HyperFlex™ Bunion Correction System is intended for use in reconstruction (correction) of the hallux valgus deformity by holding the reduction of the 1st metatarsal-2nd metatarsal intermetatarsal (IM) angle in adults and pediatric patients aged ≥13 years in which growth plates have fused.

Device Description:
The FootBridge Medical HyperFlex™ Bunion Correction System is an implantable device and accompanying instrumentation used to treat a hallux valgus deformity (bunion). It includes components that attach to the 1st and 2nd metatarsals which are joined by a suture. The system reduces the IM angle between the 1st and 2nd metatarsal without restricting range of

motion in the sagittal plane. The implant will be offered in several sizes to fit the anatomical needs of the patient population.

Predicate Device:
FootBridge Medical submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, HyperFlex™ System is substantially equivalent in indications, design principles, and performance to the following predicate device:

- **Primary Predicate:** Arthrex Mini TightRope and the Mini TightRope FT (Arthrex, K090107)

Performance Testing Summary:
The following bench testing has been conducted on the HyperFlex™ Bunion Correction System:

- Static and Fatigue Tensile Testing
- Screw Torsional Strength Testing per ASTM F543
- Screw Insertion Torque Testing per ASTM F543
- Screw Pullout Strength Testing per ASTM F543
- Particulate Testing per ASTM F1877
- Additive Manufacturing Characterization

Technological Similarities / Differences:
The subject devices were demonstrated to be substantially equivalent to the predicate cited above with respect to indications, function, and performance. The subject and predicate device have similar technological characteristics and the non-clinical tests performed by the company demonstrated that the HyperFlex™ Bunion Correction System is able to withstand physiological loading and is substantially equivalent to the predicate device.

Conclusion:
The subject device and the predicate device have the same intended use and have similar technological characteristics. The data included in this submission demonstrate substantial equivalence to the predicate device listed above.