



December 11, 2025

HyperFlex Medical
% Dave McGurl
Vice President, Regulatory Affairs - Orthopedics
MCRA
803 7th Street NW
Washington, District of Columbia 20001

Re: K252997

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: December 5, 2025
Received: December 5, 2025

Dear Dave McGurl:

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, M.S.

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.

K252997

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Please provide the device trade name(s).

?

HyperFlex® Bunion Correction System

Please provide your Indications for Use below.

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The HyperFlex® 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.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Device Trade Name: HyperFlex[®] Bunion Correction System

Manufacturer: **HyperFlex[®] Medical**
2929 Lapeer Road
Port Huron, MI 48060
(810) 982-7777

Official Correspondent: Dave McGurl
MCRA, LLC
803 7th Street, NW, 4th Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: December 10, 2025

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 Code: HRS, HWC

Primary Predicate: HyperFlex Medical (formerly FootBridge Medical) HyperFlex Bunion Correction System (K241995)

Reference Device: Arthrex Mini TightRope and the Mini TightRope FT (Arthrex, K090107)

Indications For Use:

The HyperFlex[®] 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 HyperFlex[®] Medical HyperFlex Bunion System is an implantable device and accompanying instrumentation used to treat a hallux valgus deformity (bunion). It includes an implant with components that attach to the 1st and 2nd metatarsals which are joined by a flexible central section.

The system holds the IM angle between the 1st and 2nd metatarsal without restricting range of motion. The implant will be offered in several sizes to fit the anatomical needs of the patient population.

Predicate Device:

HyperFlex® 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 devices:

- **Primary Predicate:** HyperFlex Medical (formerly FootBridge Medical) HyperFlex Bunion Correction System (K241995).
- **Reference Device:** 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 F543-17
- Screw Insertion Torque Testing per ASTM F543-17
- Screw Pullout Strength Testing per ASTM F543-17
- Particulate Testing per ASTM 1877-16
- Additive Manufacturing Characterization

Substantial Equivalence:

The subject device differs from the primary predicate device because the subject metatarsal components are manufactured from titanium alloy, whereas the predicate components are manufactured from stainless steel. Also, there have been changes to the packaging and sterilization methods. The subject devices were demonstrated to be substantially equivalent to the predicates cited above with respect to indications, design materials, function, manufacturing, and performance. 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 devices.

Conclusion:

The subject device and the predicate devices have the same intended use, the same design and similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the identified predicate devices. The HyperFlex® System is as safe, as effective, and performs as well as, or better, than the predicate devices.