



October 29, 2025

Wright Medical Technology, Inc (Stryker Corporation)  
Rachel Warnock  
Staff Regulatory Affairs Specialist  
1023 Cherry Rd  
Memphis, Tennessee 38117

Re: K251643

Trade/Device Name: Synchfix EVT

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: HTN, HRS

Dated: September 19, 2025

Received: September 19, 2025

Dear Rachel Warnock:

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](mailto: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

Submission Number (if known)

K251643

Device Name

Synchfix EVT

Indications for Use (Describe)

Synchfix EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

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: Synchfix™ EVT

- (a)(1). Submitted By:** Wright Medical Technology, Inc.  
1023 Cherry Road  
Memphis, TN 38117
- Date:** October 28<sup>th</sup>, 2025
- Contact Person:** Rachel Warnock  
Staff Specialist, Regulatory Affairs
- Secondary Contact:** Alayne Melancon  
Manager, Regulatory Affairs
- (a)(2). Proprietary Name:** Synchfix™ EVT
- Common Name:** Washer, Bolt, Nut
- Classification Name and Reference:** 21 CFR 888.3030 – Single/multi component metallic bone fixation appliances and accessories
- Device Product Code, Device Panel:** HTN – Orthopedic  
HRS – Orthopedic
- (a)(3). Primary Predicate Device(s):** GRAVITY™ Syndesmosis LP (K170249)

### **(a)(4). Device Description**

The subject device, Synchfix™ EVT, is a sterile, single-use, suture-button system intended to stabilize syndesmotic disruptions in the ankle. The subject system consists of a UHMWPE suture tensioned between two titanium alloy buttons and single use instruments to assist in implantation, including a pre-loaded inserter.

### **(a)(5). Indications for Use**

Synchfix™ EVT is intended for soft tissue and bone fixation for ankle syndesmosis disruptions with or without ankle fractures and as an adjunct in connection with hardware for ankle fractures such as Weber B, Weber C and Maisonneuve in adult and adolescent patient populations.

### **(a)(6). Technological Characteristics Comparison**

The subject Synchfix™ EVT is substantially equivalent to the predicate device in material and design.

There is no change in the fundamental scientific technology shared by both the subject and predicate devices. The subject and predicate implants have similar materials, design features, instrumentation, and performance characteristics. Mechanical testing has



confirmed substantial equivalence of the subject device, demonstrating that the technological characteristics do not raise new questions of safety or effectiveness.

The Indications for Use of the subject device differ from those of the predicate device in that the subject device is intended for use in both adolescent and adult patient populations. Additionally, the subject device's Indications for Use include the addition of Maisonneuve fractures.

**(b)(1). Substantial Equivalence - Non-Clinical Evidence**

Non-clinical performance bench testing (static pullout strength and dynamic fatigue mechanical testing) was performed to demonstrate substantial equivalence to the predicate device.

**(b)(2). Substantial Equivalence - Clinical Evidence**

N/A - Clinical testing was not necessary for the determination of substantial equivalence.

**(b)(3). Substantial Equivalence - Conclusions**

The subject device and predicate device share similar design features, basic fundamental scientific technology, principles of operation, materials, and intended use. The differences between the subject device and predicate device do not raise any new questions of safety or effectiveness. From the evidence submitted in this Traditional 510(k), the subject device can be expected to perform at least as well as the predicate device and are substantially equivalent.