March 23, 2026

Stabiliz Orthopaedics, Inc.
℅ Hannah Irwin
Director, Regulatory Affairs
MCRA
803 7th St. NW, 4th Floor
Washington, District of Columbia 20001

Re: K260112
Trade/Device Name: QuikFix External Fixator: Knee-Spanning Pack
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Codes: KTT, JDW
Dated: January 14, 2026
Received: January 14, 2026

Dear Hannah Irwin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.03.23 15:30:54 -04'00'

for Lixin Liu, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty 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. | K260112 |

Please provide the device trade name(s).

QuikFix External Fixator: Knee-Spanning Pack

Please provide your Indications for Use below.

The QuikFix External Fixator: Knee-Spanning Pack is indicated for treatment of long bone fractures of the leg that require external fixation. Specifically, the system is intended for:

- Temporary stabilization of open or closed acute fractures with lower limb soft tissue injuries;
- Temporary stabilization of lower limb fractures in the context of polytrauma;
- Temporary stabilization of lower limbs after removal of total joint (knee, and ankle) arthroplasty for infection or other failure;
- Temporary stabilization of lower limb non-unions;
- Intra-operative temporary stabilization tool of the lower limb to assist with indirect reduction.

QuikFix External Fixator: Knee-Spanning Pack is intended for use in a non-weight bearing patient.

QuikFix External Fixator: Knee-Spanning Pack components are for single use only and are suitable for use in an MR environment.

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

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

## *510(k) Summary*

| | |
|---|---|
| **Device Trade Name:** | QuikFix External Fixator: Knee-Spanning Pack |
| **Manufacturer:** | Stabiliz Orthopaedics, Inc.<br>600 Eagleview Blvd<br>Unit 300<br>Exton, PA 19341 |
| **Contact:** | Douglas L. Cerynik, MD<br>President & CEO<br>Stabiliz Orthopaedics, Inc. |
| **Prepared by:** | MCRA, LLC<br>803 7th Street, NW, 4th Floor<br>Washington, DC 20001<br>Office: 202.552.5800 |
| **Date Prepared:** | January 14, 2026 |
| **Regulation:** | 21 CFR 888.3030 |
| **Class:** | II |
| **Product Codes:** | KTT, JDW |
| **Primary Predicate:** | CITIEFFE Dolphix® External Fixation System MR Conditional (K163323) |
| **Reference Device:** | Smith and Nephew Jet-X® Bar System Clamps, Bars and Posts - MR Conditional (K072212)<br><br>Stryker Hoffman 3 Modular External Fixation System (K122284) |

**Indications For Use:**
The QuikFix External Fixator: Knee-Spanning Pack is indicated for treatment of long bone fractures of the leg that require external fixation. Specifically, the system is intended for:

- Temporary stabilization of open or closed acute fractures with lower limb soft tissue injuries;
- Temporary stabilization of lower limb fractures in the context of polytrauma;
- Temporary stabilization of lower limbs after removal of total joint (knee, and ankle) arthroplasty for infection or other failure;

- Temporary stabilization of lower limb non-unions;
- Intra-operative temporary stabilization tool of the lower limb to assist with indirect reduction.

QuikFix External Fixator: Knee-Spanning Pack is intended for use in a non-weight bearing patient.

QuikFix External Fixator: Knee-Spanning Pack components are for single use only and are suitable for use in an MR environment.

**Device Description:**
QuikFix External Fixator: Knee-Spanning Pack includes various elements designed to build a fixator construct. The system includes fixation pins, clamps and rods.

**Substantial Equivalence:**
The subject device and the predicate devices have the same intended use, have 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 predicate device. QuikFix External Fixator: Knee-Spanning Pack is as safe, as effective, and performs as well as, or better, than the identified predicate device.

**Performance Testing Summary:**
All necessary testing has been performed for the "worst-case" components of the QuikFix External Fixator: Knee-Spanning Pack to assure substantial equivalence to its predicate and to demonstrate the subject devices perform as intended. All testing was performed on test units representative of or worst-case compared to the finished device. The following evaluations were conducted to characterize the devices:

- Axial/Torsional Load to Bar and Pin Test per ASTM F1541, Annex 4
- Dynamic Construct Testing
- MRI Safety Testing per ASTM F2052-21 and ASTM F2213-17

**Conclusion:**
The subject device and the predicate devices have the same intended use and have similar technological characteristics. All performance testing conducted for the QuikFix External Fixator: Knee-Spanning Pack met the acceptance criteria or were otherwise considered acceptable. As such, the QuikFix External Fixator: Knee Spanning Pack is substantially equivalent to the predicate devices for the intended use.