August 8, 2025

AMDT Holdings, Inc
Patrick Mullaney
Authorized Contact
328 Poplar View Lane
Suite 2
Collierville, Tennessee 38017

Re: K250472
Trade/Device Name: SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, HTY, OSN
Dated: July 7, 2025
Received: July 8, 2025

Dear Patrick Mullaney:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250472

Device Name

SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)

Indications for Use *(Describe)*

SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS) is intended to be used for posttraumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudo-arthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

The SixFix™ web application for the DACS software can be used with the SixFix™ Hexapod fixator. Use of the software is optional for clinicians using the SixFix™ Hexapod fixator.

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
SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)

Submitter and Contact Person:

Patrick Mullaney

AMDT Holdings, Inc.

328 Poplar View Lane, Suite 2
Collierville, TN 38017

Patrick@mullaneymedical.com

901-853-4366

Date of summary: August 8, 2025

Device:

Proprietary Name: SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)

Common Name: Orthopedic software

Regulatory Class: Class II

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

Device Product Codes: KTT (primary), HTY, OSN

Panel: Orthopedic

Predicate Device:

K190069, SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS)

Intended Use and Indications for Use:

SixFix™ Hexapod Fixator and Deformity Analysis and Correction Software (DACS) is intended to be used for posttraumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudo-arthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

The SixFix™ web application for the DACS software can be used with the SixFix™ Hexapod fixator. Use of the software is optional for clinicians using the SixFix™ Hexapod fixator.

Device Description:

The SixFix™ Deformity Analysis and Correction Software (DACS) can be used with the SixFix™ Hexapod fixator (K190069), otherwise known as a spatial frame external fixator. Use of the software is optional for clinicians using the SixFix™ Hexapod, which is a circular external fixator based on Illizarov principles. The software utilizes radiographs, along with surgeon inputs, to develop a patient prescription to correct the deformity.

Comparison with the Predicate:

The predicate device is an older version of the SixFix™ DACS software, which is installed locally on ob the shelf computer hardware. The version of the software that is the subject of this 510(k) is a web-based version. The indications for use, user inputs, device outputs, and principle of operations of the subject device are identical to those of the predicate. The subject device runs on updated operating systems and includes support for up to date web browsers. It includes minor changes in image formats and an additional (optional) user role.

Similar risks were identified across the two devices, and similar risk mitigations were implemented. The same recognized standards are applicable to both devices, and the same test methods and basic pass/fail criteria were used.

Testing and Performance:

Software verification and validation testing were conducted and Enhanced Level documentation was provided as recommended by FDA's Guidance for Industry and FDA Stab "Content of Premarket Submissions for Device Software Functions" dated June 14, 2023.

Functional testing used the same approach as testing for the predicate device and included 43 test cases representing a range of clinical scenarios to ensure the device performed as intended. Test cases also ensured correct implementation of software requirements and risk mitigations.

Test results demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicates.

Conclusions:

A review of the device indications and technological characteristics confirms that the SixFix™ Deformity Analysis and Correction Software is substantially equivalent to the predicate device. The difference between the subject device and predicate do not raise different questions of safety or effectiveness. Therefore, we conclude that the subject device is substantially equivalent to the predicate device.