June 13, 2025

Dev4
Lance Terrill
CTO
1002 Gemini Street, Suite 129
Houston, Texas 77058

Re: K250251
Trade/Device Name: Eleganz Fusion Screw System (Fusion Screw System)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 24, 2025
Received: January 28, 2025

Dear Lance Terrill:

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)*

K250251

Device Name

Eleganz Fusion Screw System (Fusion Screw System)

Indications for Use *(Describe)*

The Eleganz™ Fusion Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, and bunionectomies.

The screws are not intended for interference or soft tissue fixation.

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) #: K250251

510(k) Summary

Prepared on: 2025-06-12

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Contact	Mr. Lance Terrill
Correspondent Contact Email	lance@dev-4.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Eleganz Fusion Screw System (Fusion Screw System)
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230744	Acutrak 3 Headless Compression Screw System	HWC
K190324	Cannulated Screw System	HWC
K131620	Jones FX System	HWC

Device Description Summary

21 CFR 807.92(a)(4)

The EleganzTM Fusion Screw System includes screws for bone fixation and a set of instruments used for screw site preparation and delivery. The device is offered in two non-sterile trays that contain the screw, Kirschner wire, bone preparation instrumentation and a driver.

The screws and Kirschner wires are used to stabilize a fracture, osteotomy site, or joint so that healing and fusion may occur which achieves its intended function.

The screws are available in solid and cannulated versions and are made from Ti6Al4V alloy. They range from 8-50 mm in length. The outer diameter is tapered, varying from 2.5 mm at the tail to 2.0 mm (solid) or 2.25 mm (cannulated) at the tip. The Kirschner wires are 316 stainless steel.

The instrumentation includes a drill, driver handle, driver bit, depth gauge / countersink, Kirschner wire, and ball and socket reamers. The drills and driver components are cannulated. The drills are offered in two lengths. The driver handle is used with the driver bit to insert the screw as well as with the drill for hand drilling. The depth gauge measures the Kirschner wire to determine its depth in the bone. The countersink has cutting flutes for easier entry into the intramedullary canal. The ball and socket reamers create a spherical radius on joint surfaces for better bony fusion.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Eleganz™ Fusion Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Examples include scaphoid and other carpal fractures, metacarpal and phalangeal fusions, and bunionectomies.

The screws are not intended for interference or soft tissue fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications For Use for the Eleganz Fusion Screw System device is the same as the primary predicate - Acutrak Fusion Screw System and similar to the secondary predicate - Cannulated Screw System.

Technological Comparison 21 CFR 807.92(a)(6)

The Dev4 Eleganz screw implants have similar technological characteristics in design, material, principle of operation as the Acutrak 3 and the Cannulated Screw predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was conducted in accordance with ASTM F543-17 (Standard Specification and Test Methods for Metallic Medical Bone Screws), FDA Guidance Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway, and in comparison to screws cleared under the predicate devices.

No clinical tests were submitted, referenced or relied for the 510(k).

Based on the indications for use, technological characteristics, and the summary of data submitted, Dev4 has determined that the subject device does not raise different questions of safety and effectiveness compared to the predicate devices. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.