



October 10, 2025

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

Re: K252312

Trade/Device Name: Eleganz IM Threaded Nail System (IM Threaded Nail System)  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: October 3, 2025  
Received: October 3, 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](mailto: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

## Indications for Use

Submission Number (if known)

K252312

Device Name

Eleganz IM Threaded Nail System (IM Threaded Nail System)

Indications for Use (Describe)

The Eleganz™ IM Threaded Nail 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 nails 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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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Eleganz IM Threaded Nail System (IM Threaded Nail 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
K120493	Mini Cannulated Titanium Headed and Headless Screw Set	HWC
K183603	Innate Intramedullary Threaded Nail System	HWC

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Device Description	<p>The Eleganz™ IM Threaded Nail System includes nails for bone fixation and a set of instruments used for nail site preparation and delivery. The device is offered in one non-sterile tray that contains the nails, Kirschner wire, bone preparation instrumentation and drivers.</p>
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The nails are used to stabilize a fracture, osteotomy site, or joint so that healing and fusion may occur which achieves its intended function.

The nails are made from 316L stainless steel. They range from 11-75 mm in length.

The instrumentation includes a reamer, driver handle, driver bit, depth gauge, countersink, and Kirschner wire. The drills and driver components are cannulated. The driver handle is used with the driver bit to insert the screw as well as with the reamer for hand reaming. The countersink has cutting flutes to ease entry of the nails into the intramedullary canal.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Eleganz™ IM Threaded Nail 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 nails 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 IM Threaded Nail System device is the same as the primary predicate - Acutrak Fusion Screw System and similar to the additional predicates - Mini Cannulated Screw System and Innate Intramedullary Threaded Nail System.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

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

## Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Testing was performed per the FDA's Guidance document, "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway," issued on November 22, 2024. The device analysis and test program followed the requirements of and met the acceptance criteria in this guidance document. The biocompatibility evaluation leveraged equivalence in materials and manufacturing to previously cleared devices (K112254, K121004, K250251). The results of this testing and evaluation demonstrated substantial equivalence of the subject devices.