



September 23, 2026

MedShape, Inc.
Lauren Livsey
Regulatory Affairs Specialist
1575 Northside Dr.
Suite 440
Atlanta, Georgia 30318

Re: K260995

Trade/Device Name: DynaNail Helix® Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: August 21, 2026
Received: August 24, 2026

Dear Lauren Livsey:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,


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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260995

?

Please provide the device trade name(s).

?

DynaNail Helix® Fixation System

Please provide your Indications for Use below.

?

The DynaNail Helix® Fixation 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 such as short bones, long bones, and small or large fragments in the foot and ankle.

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](#))

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510(k) Summary

This 510(k) Summary for the DynaNail Helix® Fixation System is provided as required by section 807.92(c).

- A. Sponsor/Applicant: MedShape, Inc. (d/b/a, Enovis Foot and Ankle)
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318
(877) 343-7016
- B. Company Contact: Vladislava Zaitseva
Regulatory Affairs
(678) 235-3339
Vladislava.Zaitseva@enovis.com
- C. Date Prepared: August 21, 2026
- D. Device Information:
Trade Name: DynaNail Helix® Fixation System
Common Name: Smooth or threaded metallic bone fixation fastener
Classification Name: Screw, Fixation, Bone
Regulation Number: 21 CFR 888.3040
Product Code: HWC
Device Classification: Class II
Panel: Orthopedic
- E. Device Description:
As pertaining to the line extension –
DynaNail Helix® Fixation System consists of the following components:
 - Implant (Threaded Bone Fastener)
 - Inserter Assembly (Attached to device)
The DynaNail Helix Threaded Bone Fastener is manufactured from nickel titanium alloy (NiTiNOL) and titanium alloy (Ti-6Al-4V ELI) and is available in multiple lengths and diameters.
The DynaNail Helix Fixation System is implanted using the Ancillary Surgical Instruments.
- F. Indications for Use:
The *DynaNail Helix® Fixation 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 such as short bones, long bones, and small or large fragments in the foot and ankle.
- G. Substantial Equivalence:
The proposed devices are substantially equivalent in intended use and fundamental scientific technology to their respective predicate devices listed below:

Predicate Device	Manufacturer	510K #	Date Cleared
DynaNail Mini	MedShape, Inc.	K182677	02/14/2019
DynaFuse Fixation System (Primary)	MedShape, Inc.	K203595	01/04/2022
DynaNail Helix	MedShape, Inc.	K254110	03/18/2026
Tiger Cannulated Screw System	Trilliant Surgical Ltd	K153338	01/14/2016

H. Basis for Submission:

This Traditional 510(k) submission serves as notification to the agency of a line extension to the DynaNail Helix Fixation System Device Family.

I. Technological Characteristics:

The proposed devices maintain similar technological and performance characteristics and have similar fundamental design and intended use as their respective predicate devices. The addition of the new device does not raise new questions regarding safety or effectiveness.

J. Summary of Testing

The following non-clinical tests were conducted to demonstrate the substantial equivalence between the proposed and predicate devices:

- Static Strain per ASTM F2516
- Insertion and Removal Torque per ASTM F543
- Corrosion per ASTM F2129
- Fatigue per ASTM E606 and F2516
- Static Bend per ASTM F1264
- Dynamic Bend per ASTM F1264, Fretting Corrosion Assessment
- Axial Free Recovery per ASTM F2082
- Axial Pullout per ASTM F543
- MR per ASTM F2182

K. Conclusion:

Based on the results of the performance testing and evaluations, comparison of device design and intended use, the proposed DynaNail Helix Fixation System line extension is determined to be substantially equivalent to its predicate device. The equivalent design, materials, intended use, and performance characteristics, as well as the results of non-clinical testing, support the conclusion that the proposed device does not raise new questions of safety or effectiveness.