March 18, 2026

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

Re: K254110
Trade/Device Name: DynaNail Mini; DynaNail Hybrid; DynaNail Helix; DynaClip; DynaClip Forte; DynaClip Delta; DynaClip Quattro
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN, JDS, JDR
Dated: December 19, 2025
Received: December 19, 2025

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.

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 13484 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 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 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.	K254110

Please provide the device trade name(s).

DynaNail Mini and DynaNail Hybrid

Please provide your Indications for Use below.

The DynaNail Mini and DynaNail Hybrid System are indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of short bones, long bones, small fragments 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)

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.	K254110

Please provide the device trade name(s).

DynaNail Helix

Please provide your Indications for Use below.

The DynaNail Helix 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)

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.	K254110

Please provide the device trade name(s).

DynaClip, DynaClip Forte, DynaClip Delta, DynaClip Quattro

Please provide your Indications for Use below.

The DynaClip, DynaClip Forte, DynaClip Delta, DynaClip Quattro Bone Staples are indicated for
• Fracture, osteotomy fixation and joint arthrodesis of the hand and foot.
• Fixation of proximal tibial metaphysis osteotomy.
• Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

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

This 510(k) Summary for the DynaNail Device Family and DynaClip Device Family 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: Lauren Livsey
Regulatory Affairs
(770) 773-0831 (cell)
Lauren.Livsey@enovis.com

C. Date Prepared: March 9, 2026

D. Device Information:

Trade Name:	DynaNail Mini®, DynaNail Hybrid™
Common Name:	Smooth or threaded metallic bone fixation fastener Orthopedic Nail
Classification Name:	Smooth or threaded metallic bone fixation fastener Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3040 21 CFR 888.3030
Product Code:	HWC, JDS
Device Classification:	Class II
Panel Code:	87 Orthopedic Panel

Trade Name:	DynaNail Helix®
Common Name:	Smooth or threaded metallic bone fixation fastener
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040 21 CFR 8883030
Product Code:	HWC, HTN
Device Classification:	Class II
Panel Code:	87 Orthopedic Panel

Trade Name:	DynaClip®, DynaClip Forte®, DynaClip Delta®, DynaClip Quattro®
Common Name:	Staple, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3030
Product Code:	JDR

enovis™

Device Classification:	Class II
Panel Code:	87 Orthopedic Panel

E. Device Description:

The *DynaNail Mini*® Fusion System consists of the following components:

- Fusion Nail
  - *DynaNail Mini*® Fusion Nail
  - *DynaNail Hybrid*™ Fusion Nail
- End Cap
- Screws

The DynaNail Mini Fusion System is implanted using the DynaNail Mini Deployment Frame and Ancillary Surgical Instruments. The Fusion Nail is manufactured from nitinol and titanium alloy (Ti6Al- 4V ELI) and is available in multiple diameters and lengths. The End Cap is manufactured from titanium alloy (Ti 6Al-4V ELI). The Screws are manufactured from titanium alloy (Ti 6Al-4V ELI) and are available in a range of lengths.

The *DynaNail Helix*® Fixation System consists of the following components:

- DynaNail Helix Threaded Bone Fastener
- DynaNail Helix Washer

The DynaNail Helix Fixation System is implanted using the Ancillary Surgical Instruments. The DynaNail Helix Threaded Bone Fastener is manufactured from nickel titanium alloy and titanium alloy (Ti6Al-4V ELI) and is available in multiple lengths. The DynaNail Helix Washer is manufactured from titanium alloy (Ti6Al- 4V ELI).

The *DynaClip*®, *DynaClip Forte*®, *DynaClip Delta*®, *DynaClip Quattro*® Bone Staples are intended for internal fixation of small bones. The DynaClip Implant and Inserter comprise the DynaClip Device System. The DynaClip Implant is available in several different sizes and leg configurations.

F. Indications for Use:

The *DynaNail Mini* and *DynaNail Hybrid* Fusion System is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of short bones, long bones, small fragments or large fragments in the foot and ankle.

The *DynaNail Helix* Fusion System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusions, 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.

The *DynaClip, DynaClip Forte, DynaClip Delta, DynaClip Quattro Bone Staples* are indicated for

- Fracture, osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

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 (Primary Predicate)	MedShape, Inc.	K182677	02/14/2019
DynaNail Hybrid	MedShape, Inc.	K203381, K240530	01/15/2021 03/21/2024
DynaNail Helix	MedShape, Inc.	K203595	01/04/2022
DynaClip	MedShape, Inc.	K181781	11/05/2018
DynaClip Forte	MedShape, Inc.	K193305	04/23/2020
DynaClip Delta and Quattro	MedShape, Inc.	K220812	08/19/2022

DynaNail TTC Fusion System (K250628) was used as a reference device in this submission.

H. Basis for Submission:

This Traditional 510(k) submission serves as notification to the agency of an update to the product labeling for the DynaNail Device Family and DynaClip Device Family to include an 'MR Conditional' Magnetic Resonance (MR) Environment claim.

I. Technological Characteristics:

The proposed devices maintain the same technological and performance characteristics and have the same fundamental design and intended use as their respective predicate devices. The addition of an MR Conditional statement to the DynaNail Device Family and DynaClip Device Family labeling do not raise new questions regarding safety or effectiveness.

J. Summary of Testing

Non-clinical testing was conducted to determine the MR environment, which concluded that "MR Conditional" will be added to labeling.

- MR Testing per ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119

Evaluation of the biocompatibility, sterility, shelf life, packaging, and mechanical performance of the proposed devices leveraged identical manufacturing materials and processes, sterilization methods, and packaging to the predicate devices.

K. Conclusion:

Based on the results of the MR testing, as well as a comparison of device design and intended use, the proposed DynaNail Mini, DynaNail Hybrid, DynaNail Helix and DynaClip, DynaClip Forte, DynaClip Delta and DynaClip Quattro Bone Staples are determined to be substantially equivalent to their respective predicate device. The same and 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.