September 12, 2025

MedShape, Inc.
Vladislava Zaitseva
Director, Regulatory Affairs – Foot & Ankle
1575 Northside Dr. NW
Suite 440
Atlanta, Georgia 30318

Re: K250628
Trade/Device Name: DynaNail TTC Fusion System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 8, 2025
Received: August 14, 2025

Dear Vladislava Zaitseva:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.09.12 13:57:12 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*

K250628

Device Name

DynaNail TTC Fusion System

Indications for Use *(Describe)*

The DynaNail TTC Fusion System is intended for use in tibiotalocalcaneal fusions:
- Post-traumatic and degenerative arthritis.
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints.
- Revision after failed ankle arthrodesis with subtalar involvement.
- Failed total ankle arthroplasty.
- Non-union ankle arthrodesis.
- Rheumatoid hindfoot.
- Absent Talus (requiring tibiocalcaneal arthrodesis).
- Avascular necrosis of the talus.
- Neuroarthropathy or neuropathic ankle deformity.
- Neuromuscular disease and severe deformity.
- Osteoarthritis.
- Charcot Foot.
- Previously infected arthrosis, second degree.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary for the DynaNail TTC Fusion 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
Director of Regulatory Affairs
(706) 346-5579
vladislava.zaitsseva@enovis.com

C. Date Prepared: 11 September 2025

D. Device Information:

Trade Name:	DynaNail TTC Fusion System
Common Name:	Ankle Nail System
Classification Name:	Intramedullary fixation rod
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Device Classification:	Class II
Panel Code:	87 Orthopedic Panel

E. Device Description:

The *DynaNail TTC Fusion System* consists of the following components: the DynaNail TTC Fusion Nail, DynaNail End Cap, DynaNail Screws, and the DynaNail Deployment Frame. The DynaNail TTC Fusion Nail, DynaNail End Cap, and the DynaNail Screws are implanted into the medullary canal of the tibia, talus and calcaneus using the DynaNail Deployment Frame and Ancillary Surgical Instruments. The DynaNail TTC Fusion Nail is manufactured from nitinol and titanium alloy (Ti 6Al-4V ELI) and is available in multiple diameters and lengths. The DynaNail End Cap is manufactured from titanium alloy (Ti-6AI-4V ELI). The DynaNail Screws are manufactured from titanium alloy (Ti 6Al- 4V ELI) and are available in a range of lengths.

F. Predicate and Reference Devices:

The proposed devices are substantially equivalent in intended use and fundamental scientific technology to its predicate device MedShape, Inc.'s DynaNail TTC Fusion System cleared under 510(k) K171376 on 11/02/2017. The reference devices are Paragon 28 Inc.'s Phantom® Hindfoot TTC/TC Nail System cleared under 510(k) K251850 on 7/14/2025, and Arthrex's Dual Compression Hindfoot cleared under K221031 on 12/20/2022.

G. Basis for Submission:

This Traditional 510(k) submission notifies the agency of updates to the DynaNail TTC Fusion System that is now supplied pre-stretched, eliminating the need to stretch the Nitinol compressive element in the operating room. This change has led to updates in the design of the Nitinol compressive element, nail outer body and deployment frame.

Additionally, this Traditional 510(k) submission serves as notification to the agency of an update to the product labeling for the DynaNail TTC to include an 'MR Conditional' Magnetic Resonance (MR) Environment claim.

H. Indications for Use:

The *DynaNail TTC Fusion System* is intended for use in tibiotalocalcaneal fusions:

- Post-traumatic and degenerative arthritis.
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints.
- Revision after failed ankle arthrodesis with subtalar involvement.
- Failed total ankle arthroplasty.
- Non-union ankle arthrodesis.
- Rheumatoid hindfoot.
- Absent Talus (requiring tibiocalcaneal arthrodesis).
- Avascular necrosis of the talus.
- Neuroarthropathy or neuropathic ankle deformity.
- Neuromuscular disease and severe deformity.
- Osteoarthritis.
- Charcot Foot.
- Previously infected arthrosis, second degree.

I. Technological Characteristics:

The proposed devices maintain the same technological and performance characteristics and have the same fundamental design and intended use as its predicate device. The design modifications to the DynaNail TTC Nitinol compressive element, nail outer body and deployment frame, and addition of an MR Conditional statement to the device labeling do 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 Test per ASTM 2516
- Free Recovery Testing per ASTM F2082
- Fatigue Strain Test per ASTM E606 and ASTM F2516
- Corrosion Test per ASTM 2129
- MR Testing per ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119

K. Conclusion:

Based on the results of the performance testing and evaluations, comparison of device design and intended use, the proposed DynaNail TTC Fusion System is determined to be substantially equivalent to its 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 different questions of safety or effectiveness.