March 21, 2024

MedShape, Inc.
Amberlee Soto
Regulatory Affairs Specialist
1575 Northside Drive
Suite 440
Atlanta, Georgia 30318

Re: K240530
Trade/Device Name: DynaNail Mini Tapered Hybrid
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, JDS
Dated: February 23, 2024
Received: February 23, 2024

Dear Amberlee Soto:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240530

Device Name

DynaNail Mini Tapered Hybrid

Indications for Use *(Describe)*

The DynaNail Mini Tapered Hybrid is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of large bones in the foot and ankle.

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

Date Submitted: February 23rd, 2024.

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

MedShape, Inc. (a.k.a., MedShape, a division of ENOVIS)
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

B. Company Contact:

Amberlee Soto
Regulatory Affairs Specialist
(469) 585-6710 (direct)
amberlee.soto@enovis.com

C. Device Information:

Trade Name: *DynaNail Mini Tapered Hybrid™*
Common Name: Smooth or threaded metallic bone fixation fastener
Orthopedic Nail

D. Classification: Smooth or threaded metallic bone fixation fastener
Single/multiple component metallic bone fixation appliances, accessories
Class II, Panel Code: 87
HWC, Screw, Fixation Bone, 888.3040
JDS, Nail, Fixation, Bone, 888.3030

E. Predicate Device:

DynaNail Mini Hybrid™ (K203381)

F. Physical Description:

The proposed *DynaNail Mini Tapered Hybrid*™ is part of the DynaNail Mini™ Fusion System. The proposed implant is sterile, single use titanium device with an internal Nitinol compressive element for use in midfoot and hindfoot reconstruction. A titanium outer body provides bending and torsional rigidity to the arthrodesis construct, while the internal Nitinol compressive element sustains compression across the joints post-operatively.

The proposed *DynaNail Mini Tapered Hybrid*™ is available in identical diameters and lengths to the predicate device, and to accommodate variations in patient anatomy. The proposed device differs from the predicate device only in the threaded component major diameter, which is tapered. The *DynaNail Mini Tapered Hybrid*™ is implanted with the same driver/ deployment frame and fixation screws as the predicate. The fixation screws are single use titanium headless screws. These are available in various lengths to accommodate the anatomical fixation required. The system includes instruments for implantation identical to the predicate.

G. Indications for Use:

The *DynaNail Mini Tapered Hybrid*™ is indicated for fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of large bones in the foot and ankle.

This intended use is identical to that of the predicate device cleared under K203381.

H. Comparison to Predicate Device:

The *DynaNail Mini Tapered Hybrid*™ is substantially equivalent in Intended Use, design, function, material, diameters, and lengths to the following predicate device:

DynaNail Mini Hybrid™, Orthopedic Nail, K203381

The proposed and predicate devices are comprised of implant grade Titanium alloy and Nickel Titanium Alloy and differ only in the threaded segment, which incorporates a taper of the major diameter for the proposed device. All implants are sold sterile. Engineering analyses and mechanical performance testing (per ASTM F1264 and ASTM F543) were performed. The test results and analyses demonstrate substantial equivalent performance to the predicate device. The manufacture and processing of all patient contacting materials are identical to the predicate *DynaNail Mini Hybrid*™ K203381.

Pyrogenicity testing was conducted per ANSI/AAMI ST72 for the worst case largest *DynaNail*™ system, confirming the most loaded device scenario meets the limit of 20 EU/device. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011 (R2016).

Analysis substantiates the statement that the proposed device performs equivalently to the predicate device. Refer to Table 1 below for summary of substantial equivalence.

Table 1. Table of Substantial Equivalence

Parameter	***DynaNail Mini Tapered Hybrid* (ENOVIS Proposed)**	***DynaNail Mini Hybrid* (*Predicate*)**
Manufacturer	*ENOVIS*	*MedShape, Incorporated (now part of ENOVIS)*
510(k) Number	*Unassigned*	*K203381*
Product Code	*HWC, JDS* ***(NO CHANGE)***	
Material (nail body)	Ti-6AL-4V Titanium ***(NO CHANGE)***	
Material (dynamic element)	*NiTiNOL* ***(NO CHANGE)***	
Lengths	*60 – 140mm* ***(NO CHANGE)***	
Proximal End Fixation	*Threaded, 0.5MM TAPERED MAJOR DIAMETER*	*Threaded, NO TAPER TO MAJOR DIAMETER*
Distal End Fixation	*1 Fixation Screw* ***(NO CHANGE)***	
Outside Diameter, mm	*7mm – 8mm* ***(NO CHANGE)***	
Cross Sectional Shape	*Round* ***(NO CHANGE)***	
Potential Critical Stress Concentrators	*None* ***(NO CHANGE)***	
Insertion Mechanism	*Driver / External Frame* ***(NO CHANGE)***	
Compression Method	*External Frame and NiTiNOL Element* ***(NO CHANGE)***	
NiTiNOL Sustained Compression	*8%* ***(NO CHANGE)***	
Intended use	*Fracture fixation, osteotomies, reconstruction procedures, non-unions, and fusions of large bones in the foot and ankle* ***(NO CHANGE)***	

I. Summary of Non-Clinical Tests:

Product characterization using known standards and / or clinically relevant acceptance criteria was performed on the proposed device. A summary of this testing is provided in **Table 2**.

Table 2. Non-Clinical Testing Information

Test	*Test Summary*	*Results*
ASTM F1264-16e, Standard Specification for Intramedullary Fixation Devices	*Static Four-Point Bend*	The four-point bending strength of the proposed device was substantially equivalent to the predicate device
	Static Torsion Test	The static torsion strength of the proposed device was substantially equivalent to the predicate device
	Bending Fatigue Test	The bending fatigue strength of the proposed device was substantially equivalent to the predicate device
US FDA Guidance Document "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway", issued December 2020	*Fixation Strength (Axial Pullout) Analysis*	The axial pull-out strength of the proposed device was substantially equivalent to the predicate device
ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws, Annex A3		The distal and proximal fixation strength of the proposed device was substantially equivalent to the predicate device and / or superior to the reference value recommended per the US FDA Guidance Document "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway", issued December 2020.

J. Biocompatibility Testing:

Biocompatibility of the predicate device was deemed unnecessary since the material, processes, assembly, packaging, and sterilization of the proposed device are identical to the predicate.

K. Sterilization:

The method employed to ensure sterility of the proposed device is provided in **Table 4**. The sterilization process is identical for the subject and predicate device.

Table 4. Sterilization Information

Test	*Test Method Summary*	*Results*
Sterilization Validation	*VDmax25 per ISO/AAMI/ANSI 11137-1:2006, Sterilization of health care products- Radiation- Requirements for development, validation, and routine control of a sterilization process for medical devices*	*Pass*

L. Animal Studies:

There were no animal studies necessary to establish safety of the proposed device against the predicate device.

M. Clinical Studies:

No human studies were necessary to prove the safety and efficacy of the device.

N. Conclusion:

No new questions of safety or effectiveness were identified during device testing; therefore, the proposed device is considered substantially equivalent to the predicate device and that the proposed changes meet the requirements for Special 510(k) submission as outlined in the US FDA Guidance Document "The Special 510(k) Program" issued September 13th, 2019.