January 15, 2021

MedShape Inc
Akhilesh Gokhale
Product Manager
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

Re: K203381
Trade/Device Name: DynaNail Mini 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: October 21, 2020
Received: November 17, 2020

Dear Akhilesh Gokhale:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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)*
K203381

Device Name
DynaNail Mini Hybrid™

Indications for Use *(Describe)*
The DynaNail Mini™ Fusion System 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.

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510(k) Summary

510(k) Number: K203381

Date Submitted: October 21, 2020

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

A. Submitter:

MedShape, Inc.
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

B. Company Contact:

Akhilesh Gokhale
Product Manager, Research & Development
(678) 235-3322 (direct)
(404) 249-9158 (fax)
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C. Device Information:

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

D. Classification Name:

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

E. Predicate Device(s):

DynaNail Mini™, Orthopedic Nail, K182677

This statement is based on the similarity of the subject device to the predicate devices in one or more of intended use, materials, design and principles of operation.

F. Physical Description:

The proposed DynaNail Mini Hybrid™ is part of the DynaNail Mini™ Fusion System. The proposed implant is sterile, single use titanium device with an additional 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 DynaNail Mini Hybrid™ is available in multiple diameters and lengths to accommodate variations in patient anatomy. The DynaNail Mini Hybrid™ is implanted with a driver/ deployment frame and fixation screws. 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.

G. Indications for Use:

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

H. Comparison of Technological Characteristics:

The DynaNail Mini Hybrid™ is substantially equivalent in Intended Use, design, function, material, diameter and length to the following predicate devices:

DynaNail Mini™, Orthopedic Nail, K182677

The proposed and predicate devices are comprised of implant grade Titanium alloy and Nickel Titanium Alloy. All implants are sold sterile. In addition to engineering analysis, the device was subjected to following performance tests to support the assertion of substantial equivalence:

- Static Torsion test per ASTM F543
- Static Axial Strain test per ASTM F2516
- Fatigue Strain test per ASTM E606

The test results and analysis demonstrate substantial equivalent performance to the predicate device.

The manufacture and processing of all patient contacting materials are identical to the predicate DynaNail Mini™ K182677.

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 20EU. 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.