MedShape, Inc.
Courtney Kline
Product Engineer
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

November 2, 2017

Re: K171376
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: October 16, 2017
Received: October 18, 2017

Dear Courtney Kline:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171376

Device Name
DynaNail TTC Fusion System

Indications for Use *(Describe)*
The DynaNail TTC Fusion System is intended for tibio-talo-calcaneal 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.

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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

510(k) Number: K171376

Date Prepared: October 16, 2017

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

A. Submitter:

MedShape, Inc.
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B. Company Contact:

Courtney Kline
Product Engineer
(678) 235-3316 (direct)
(404) 249-9158 (fax)
courtney.kline@medshape.com

C. Device Information:

Trade Name: *DynaNail™ TTC Fusion System*
Common Name: Ankle Nail System

D. Classification Name: Intramedullary Fixation Rod
HSB 21 CFR 888.3020

E. Predicate Device(s):

DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K101934
DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K113828

F. Physical Description:

The proposed DynaNail™ is a sterile, single use titanium device with an additional internal Nitinol compressive element for use in tibiotalocalcaneal fusions. The DynaNail™'s titanium outer body provides bending and torsional rigidity to the arthrodesis construct, while the internal Nitinol compressive

element sustains compression across the ankle and subtalar joints post-operatively.

The DynaNail™ is available in 10, 11, and 12mm diameters and lengths of 180mm, 220mm, 260mm, and 300mm. The DynaNail™ is implanted with a deployment frame and fixation screws. The fixation screws are single use 5mm titanium headed and headless screws. The screws are available in lengths that range from 20 to 110mm.

G. Indications for Use:

The DynaNail™ TTC Fusion System is intended for tibio-talo-calcaneal 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.

H. Comparison of Technological Characteristics:

The DynaNail™ is substantially equivalent in design, function and intended use to the following predicate devices:

DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K101934
DynaNail™ Ankle Nail, Intramedullary Fixation Rod, K113828

The only changes to nail design relative to that of the predicate submission K113828 are two positional changes and one additional hole for fixation screw placement in the 260mm and 300mm nail lengths only, and an

additional taper in diameter for the 12mm nails of 260mm and 300mm lengths only. Other changes in this submission include three additional screw length offerings and minor updates to the deployment technique.

The construction of the DynaNail™ body is equivalent to that of the previously cleared DynaNail™ devices. The manufacture and processing of all patient contacting materials are identical to the predicate DynaNails™ K101934 and K113828. The DynaNail™ device is offered in the same diameters (10-12mm) and lengths (180-300mm) as the predicate DynaNail™ K113828. The DynaNail™ utilizes an equivalent deployment method and external frame technology as the predicates DynaNail™ K101934 and K113828.

Functional performance analysis of the predicates and proposed DynaNail™ were conducted per ASTM F 1264-03. Analysis substantiates the statement that the proposed device performs equivalently to the predicate devices.

Pyrogenicity testing was conducted per ANSI/AAMI ST72 for the DynaNail™ system, confirming the most loaded device scenario meets the limit of 20EU.

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Product Engineer

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