January 4, 2022

MedShape, Inc.
Ryan O'flaherty
Product Manager
1575 Northside Drive NW, Suite 440
Atlanta, Georgia 30318

Re: K203595
Trade/Device Name: DynaFuse Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: November 29, 2021
Received: December 1, 2021

Dear Ryan O'flaherty:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203595

Device Name
DynaFuse Fixation System

Indications for Use *(Describe)*
The MedShape DynaFuse Fixation System 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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: K203595

Date Submitted: December 7th, 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:
Ryan O'Flaherty
Product Manager
(404) 249-9155
(404) 249-9158 (fax)
ryan.oflaherty@medshape.com

C. Device Information:
Trade Name: DynaFuse™ Fixation System
Common Name: Smooth or threaded metallic bone fixation fastener

D. Device Classification:
Class II
21 CFR 888.3040 (Primary)
Smooth or threaded metallic bone fixation fastener
Panel Code: 87, Orthopedic Panel
Product Code: HWC

Class II
21 CFR 888.3030
Single/multiple component metallic bone fixation appliances and accessories
Panel Code: 87, Orthopedic Panel
Product Code: HTN

E. Predicate Devices:
Trilliant Surgical Tiger Cannulated Screw, K153338 (Primary)
Tyber Medical Trauma Screw, K133842 and K153575

F. Referenced Predicate Devices:
MedShape DynaNail Mini, K182677

G. Physical Description:
The proposed MedShape DynaFuse Fixation System is a sterile, single use orthopedic implant system consisting of a threaded bone fastener and washer. The DynaFuse Fixation System is designed to apply compression across a target fracture or fusion site and is intended to be used for fracture and osteotomy fixation, including joint arthrodesis. The devices provided sterile, intended for single use, and are comprised of titanium alloy and nickel-titanium.

H. Indications for Use:
The MedShape DynaFuse Fixation System 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.

I. Comparison of Characteristics / Performance Testing / Substantial Equivalence:
The MedShape DynaFuse Fixation system and its predicate devices have similar indications for use, design, materials, and technological principles of operation.

The following non-clinical tests were performed to demonstrate substantial equivalence to the predicate devices:

- Static Torsion Test per ASTM F543
- Static Strain Test per ASTM F2516
- Fatigue Strain Test per ASTM E606
- Bacterial endotoxin testing based on an endotoxin limit of 20EU/device per ANSI/AAMI ST72:2011

Additional engineering analysis of the MedShape DynaFuse Fixation System and the predicate devices was also performed to demonstrate substantial equivalence.

No new questions of safety or effectiveness were identified during device testing and analysis; therefore, the DynaFuse Fixation System is considered substantially equivalent to the predicate devices.

Ryan O'Flaherty
Product Manager
(404) 249-9155
(404) 249-9158 (fax)
ryan.oflaherty@medshape.com