August 19, 2022

MedShape, Inc.
Courtney Kline
Engineering Manager
1575 Northside Dr. NW, Suite 440
Atlanta, Georgia 30318

Re: K220812
Trade/Device Name: *DynaClip*® Bone Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: July 21, 2022
Received: July 22, 2022

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. 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,

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220812

Device Name
DynaClip® Bone Staple

Indications for Use *(Describe)*
-Fracture, osteotomy fixation and joint arthrodesis of the hand and foot.
-Fixation of proximal tibial metaphysis osteotomy.
-Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

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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510(k) Summary

510(k) Number: K220812

Date Submitted: August 19th, 2022

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
(404) 249-9155

B. Company Contact:

Courtney Kline
Engineering Manager
(727) 543-6624 (direct)
(404) 249-9158 (fax)
courtney.kline@djoglobal.com

C. Device Information:

Trade Name: *DynaClip®* Bone Staple
Common Name: Staple, Fixation, Bone

D. Classification: Orthopedic Panel
JDR, 21 CFR 888.3030
Class II

E. Predicate Device:

MedShape *DynaClip®* Bone Staple, K193305

F. Physical Description:

The proposed MedShape *DynaClip®* Bone Staple is a sterile, single use orthopedic implant designed to use the principles of interference fit to hold the implant body into a predrilled hole and across the target fracture site. The *DynaClip®* Bone Staple is intended to be used for fracture and osteotomy fixation, including joint arthrodesis, and fixation of small bone fragments, and is comprised of Nickel Titanium alloy commonly referred to as NiTiNOL (reference ASTM F2063, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants). The staple is provided pre-loaded on a disposable inserter.

G. Indications for Use:

- Fracture, osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.

- Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

H. Comparison of Characteristics / Performance Testing / Substantial Equivalence:

The MedShape *DynaClip®* Bone Staple was designed to have equivalent technological characteristics as the previously cleared MedShape *DynaClip®* Bone Staple device, cleared under K193305. They both have the same materials (NiTiNOL construction as per ASTM 2063, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants), method of operation (pre-loaded on an inserter), method of sterilization (gamma irradiation), and operate under the same principles of interference fixation and sustained compression to promote fusion of bone. The devices differ only by cross-section and physical size configurations offered. MedShape asserts that any differences from the predicate device do not affect safety or effectiveness.

In addition, the proposed device was subjected to the following performance tests to support the assertion of substantial equivalence*:*

- Corrosion resistance testing per ASTM F2129, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
- Transformation temperature thermal analysis testing per ASTM F2004-17, Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis
- Bacterial endotoxin testing based on an endotoxin limit of 20EU/device per ANSI/AAMI ST72:2011
- Mechanical comparison via Finite Element Analysis
- No clinical data was collected, as it was deemed unnecessary to support the assertion of safety

No new questions of safety or effectiveness were identified during device testing; therefore, the *DynaClip®* Bone Staple is considered substantially equivalent to the predicate device.