



510(k) Summary

Date Submitted: September 5, 2013

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

- A. Submitter:
MedShape, Inc.
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Atlanta, Georgia 30318
- B. Company Contact:
Stephen Laffoon
Sr. Research & Development Engineer
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stephen.laffoon@medshape.com
- C. Device Information:
Trade Name(s): *ExoShape® Duo* Soft Tissue Fastener

Common Name(s): Fastener, Fixation, bone
- D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
HWC/MBI 21 CFR 888.3040
- E. Predicate Device(s):
MedShape, Inc., *ExoShape®* Soft Tissue Anchor, K101808 & K111471
MedShape, Inc., *Eclipse™* Soft Tissue Fastener, K123350
- F. Physical Description:
The proposed *ExoShape® Duo* Soft Tissue Fastener is a sterile, single use, orthopedic implant intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone. The *ExoShape® Duo* Soft Tissue Fastener is designed to use the principles of both interference fit and bearing area to reattach soft tissue intended for insertion into a hole created in bone.

The *ExoShape® Duo* Soft Tissue Fastener body is comprised of two interlocking PEEK. Both components are expanded into the bone hole, compressing the soft tissue against the bone wall and locking the implant to the bone; fastening the assembly into place.
- G. Indications for Use:
The *ExoShape® Duo* Soft Tissue Fastener is indicated for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

- Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon Reconstruction and Tendon Transfers
- Knee: Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
- Elbow: Biceps Tendon Reattachment and Ulnar or Radial collateral Ligament Reconstruction
- Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal Joint Arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and Repairs and Tendon Transfers

H. Comparison of Technological Characteristics:

The *ExoShape® Duo* Soft Tissue Fastener is substantially equivalent in function and intended use to the following predicate devices:

MedShape, Inc., ExoShape® Soft Tissue Anchor, K101808 & K111471
MedShape, Inc., Eclipse™ Soft Tissue Fastener, K123350

All fasteners are comprised of implant grade PEEK. All fasteners have the same indications for use. In addition, functional performance testing has been conducted in Sawbone® bone analogue. This testing included monotonic soft tissue fixation strength (pull-to-failure) and other dimensional verification and material safety testing (both bio and MRI compatibility). Analysis of the results supports the conclusion that the proposed device is substantially equivalent to the predicate devices.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 9, 2013

MedShape, Incorporated
Mr. Stephen Laffoon
Senior Research & Development Engineer
1575 Northside Drive Northwest, Suite 440
Atlanta, Georgia 30318

Re: K132783

Trade/Device Name: *ExoShape® Duo* Soft Tissue Fastener
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: September 5, 2013
Received: September 12, 2013

Dear Mr. Laffoon:

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

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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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132783

Device Name: *ExoShape® Duo* Soft Tissue Fastener

Indications for Use:

The MedShape, Inc., *ExoShape Duo* Soft Tissue Fastener is intended for fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

- Shoulder:** Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
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Prescription Use X AND/OR Over-The-Counter Use _____
 (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

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Division of Orthopedic Devices