K091202 (pg 1/2)

MEDSHAPE SOLUTIONS

SEP 16 2009

Special 510(k) Summary

Special 510(k) Number: _____

Date Prepared: April 23rd, 2009

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

A. Submitter:
MedShape Solutions, Inc. (**MSS**)
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Atlanta, Georgia 30318

B. Company Contact:
Jack Griffis
Vice President, Research & Development
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C. Device Information:
Trade Name: *WedgeLoc*™ 180X Suture Anchor with *Opti-Fiber*™ Sutures
Common Name: Suture Anchor

D. Classification Name: Fastener, Fixation, Non-degradable, Soft Tissue
HWC/MBI 21 CFR 888.3040
Suture, Nonabsorbable, Synthetic, Polyethylene
GAT 21 CFR 878.500

E. Predicate Device(s):
MSS, *WedgeLoc*™ Suture Anchor with *Opti-Fiber*™ Suture, K083792
Arthrex PushLock™ Suture Anchor, K051219
Arthrex FiberWIRE™ Polyblend Suture, K021434

F. Labeling and Intended Use:
NOTE: Draft labels and instructions for use can be found in Attachment D. However, no changes to the labeling or Instructions for Use have been made to the original submitted information per K083792.

The proposed *WedgeLoc*™ 180X Suture Anchor and *Opti-Fiber*™ Suture has the same intended uses as the previously cleared device (K083792). In particular, both devices are indicated for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder:	Rotator Cuff Repair, 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
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

G. Substantial Equivalence Summary:

The proposed *WedgeLoc*™ 180X Suture Anchor is is substantially equivalent to the predicate *WedgeLoc*™ Suture Anchor with *Opti-Fiber*™ Suture (K08379) and the Arthrex PushLock™ Suture Anchor (K051219) in which the basic features and intended uses are the same. In addition, the technological characteristics of the *WedgeLoc*™ 180X and the *WedgeLoc*™ Suture Anchors are equivalent. Any differences between the *WedgeLoc*™ 180X Suture Anchor and the predicate *WedgeLoc*™ or Arthrex PushLock™ Suture Anchors are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, MedShape Solutions, Inc. has determined that the new *WedgeLoc*™ 180X Suture Anchor is substantially equivalent to the currently marketed predicate device.

04/23/2009

Jack Griffis
Vice President, Research & Development

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 16 2009

MedShape Solutions
% Jack Griffis
1575 Northside Drive, Suite 440
Atlanta, Georgia 30318

Re: K091202
Trade/Device Name: WedgeLoc™ 180x Suture Anchor and Opti-Fiber™ Sutures
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, GAT
Dated: September 2, 2009
Received: September 4, 2009

Dear Mr. Griffis:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buchholz for

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

Enclosure

Indications for Use

510(k) Number: K091202

Device Name: *WedgeLoc*™ 180X Suture Anchor and *Opti-Fiber*™ Sutures

Indications for Use:

The MedShape Solutions, Inc., *WedgeLoc*™ 180X Suture Anchor with *Opti-Fiber*™ Sutures are intended for fixation of suture to bone in the shoulder, foot/ankle, knee, hand/wrist and elbow in the following procedures:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
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Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis
Hand/Wrist:	Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow:	Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial collateral Ligament Reconstruction

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKN

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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