BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Value Analysis Resource Guide
Memory Staple

Contents

Company Information

Founded in 1987, BioPro Inc. is an independently owned medical device manufacturer focused on creating solutions that improve patient's lives.

As an FDA registered and ISO certified manufacturer, BioPro designs, develops, manufactures, and distributes products for companies across the globe.

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Product Overview

Description

The Memory Staple is a nitinol memory-alloy staple designed to provide fast and stable fixation in a variety of procedures. The staple provides dynamic compression designed to facilitate bone healing.[1,2]

Benefits

- Advanced technology allows for activation at patient body temperature
- Generates dynamic compressive forces that increase overtime[2]
- Adapts to changes in joint, fracture, or osteotomy site due to resorption, movement, or bone remodeling[2]
- S-bridge design ensures even compression across fusion site
- Easy to use instrumentation for fast and direct visual insertion may reduce procedure time.
- 17 standard sizes with varying bridge widths, leg lengths, and wire sizes, allowing fixation in most hand or foot procedures

Indications for use:

1. Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
2. Fixation of soft tissue to bone.

Contraindications:

1. Comminuted bone surface which would mitigate against staple placement.
2. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
3. Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Warnings & Precautions

Warning

- Immobilization in addition to this internal fixation until bone healing should be achieved by routine methods (casting, splints, etc.)
- Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of the fracture line.
- This staple system has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment.

Adverse Effects:

- Allergic reactions to metal (titanium or nickel)
- Delayed or non-union of bone
- Delayed healing
- Staples may break
- Staples may extruded or back out of the surgical site

Caution

- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured and staple should not be used if blister or seal is damaged.
- Staples should be stored at 75° F (24°C) or less. Staples that have exceeded 75° F (24°C) must be reset prior to use by placing them in a freezer at or below -4°F (-20°C) for two hours prior to use. Once they have been reset, they must be stored at or below 75 degrees.
- The staples are a single use device.
- Do not autoclave staples.

Competition

Advantages over other Nitinol Staples include:

- Wider size range than most product offerings with 17 standard sizes.
- Smallest staple on the market at 7mm x 5mm.
- Body-heat activation allows delayed compression ensuring correct positioning.
- S-Bend bridge ensures even compression and a low profile fit.
- Convenient, reusable instrumentation reduces costs compared to disposable instruments.

Label and Packaging

Sterilized with ethylene oxide gas.

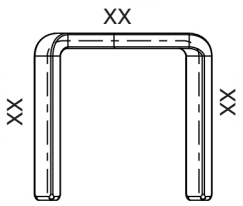
Caution

For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

MEMORY STAPLE

MEMORY STAPLE
(STAPLE SIZE)
MATERIAL: NITINOL ASTM F-2063

QTY 1



REF XXXXX	LOT XXXXXX
MFG Date YEAR-MM-DD	**Expiration Date** YEAR-MM-DD

Consult IFU

Single Use

Do not use if package is damaged

Caution

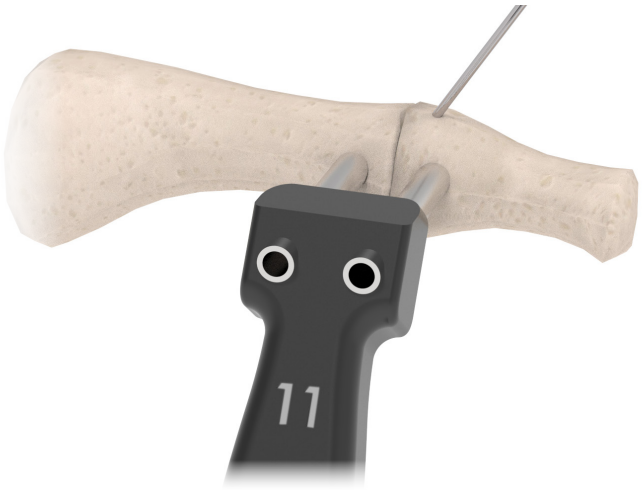
Manufactured by

STERILE EO Sterilized using ethylene oxide

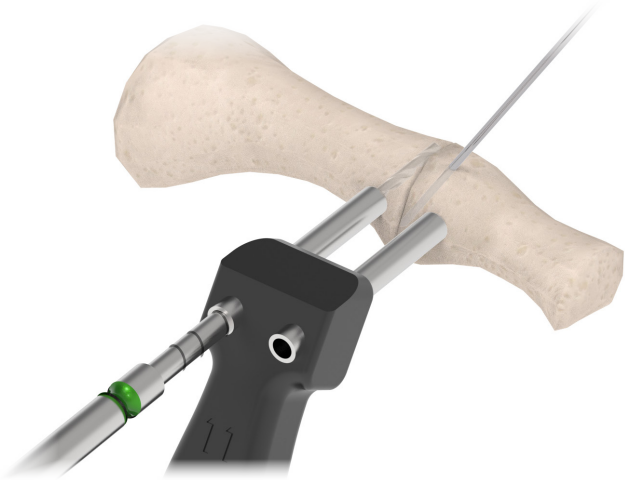
℞ Only Prescription Use Only

Instructions for Use

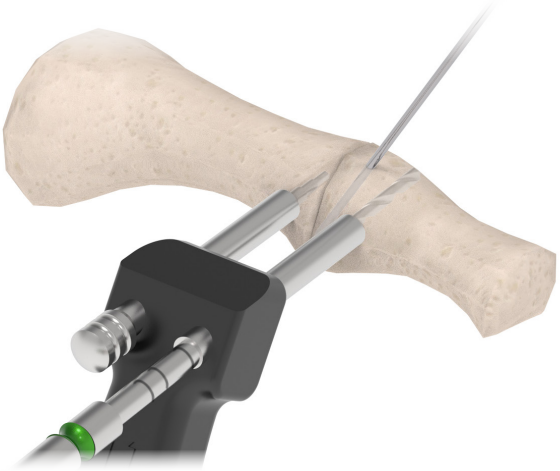
The following is an abbreviated technique. Please refer to surgical technique for complete details.



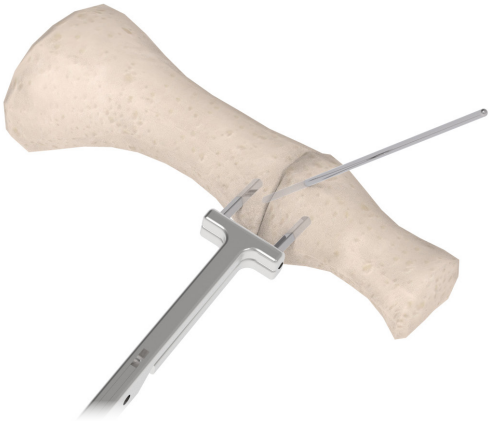
1. Prepare the surgical site and determine optimal staple size.



2. After determining the staple size, utilize the appropriately sized drill guide and drill bit to drill on one side of the fusion site.



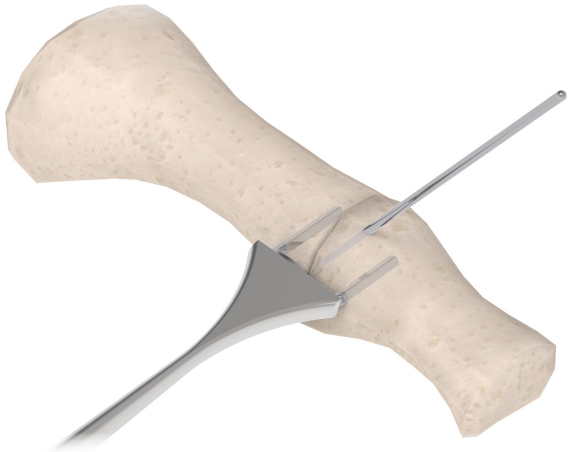
3. Insert the provided anchor pin into the drill hole to maintain position; drill for the opposite leg.



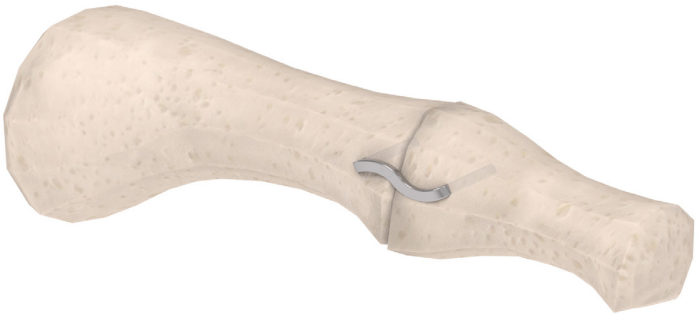
4. Utilizing a pair of the included staple clamps, remove the staple from its protective shipping block and place it into the pre-drilled holes.

Caution

It is important that the staple is always handled with staple clamps, never by hand, as this may result in premature activation.

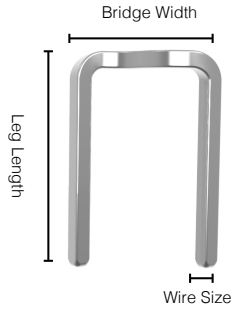


5. Use the appropriate size staple punch to ensure the staple is fully inserted and seated against the bone.



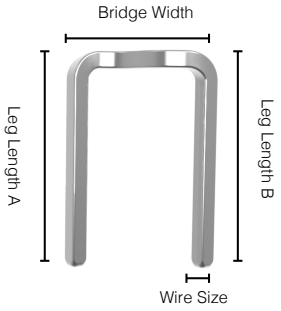
6. After insertion, the staple should sit flush against the bone. Staple compression will occur at body temperature, but may be hastened by irrigation with saline 98°F (37°C) to 100°F (38°C).

Ordering



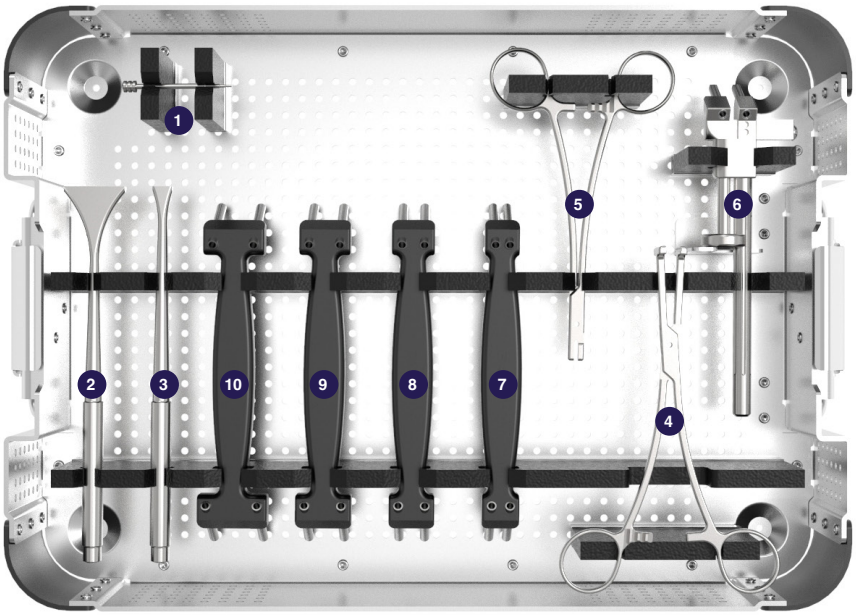
Standard Legs

Item #	Bridge Width	Leg Length	Wire Size	Drill Ø	Color Code
17637	7mm	5mm	1.2mm	1.4mm	Blue
17628	7mm	5mm	1.5mm	1.8mm	Green
17638	9mm	7mm	1.2mm	1.4mm	Blue
17629	9mm	7mm	1.5mm	1.8mm	Green
17630	11mm	8mm	1.5mm	1.8mm	Green
17631	11mm	10mm	1.5mm	1.8mm	Green
17632	13mm	10mm	1.5mm	1.8mm	Green
17633	15mm	12mm	1.5mm	1.8mm	Green
17625	15mm	12mm	2.0mm	2.4mm	Yellow
17627	20mm	20mm	2.0mm	2.4mm	Yellow
17622	20mm	20mm	2.0x3.0mm	3.0mm	Purple
17623	25mm	22mm	2.0x3.0mm	3.0mm	Purple
17624	30mm	30mm	2.0x3.0mm	3.0mm	Purple



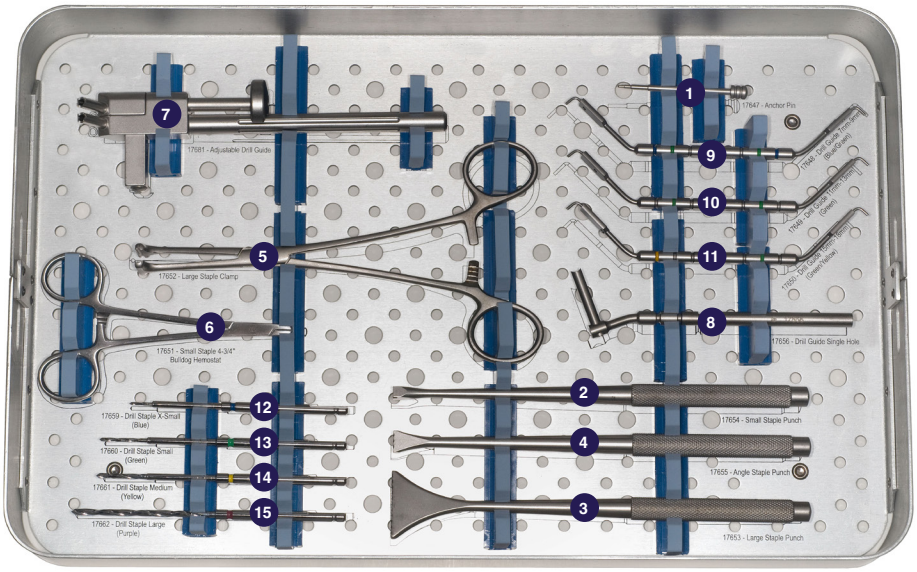
Offset Legs

Item #	Bridge Width	Leg Length A	Leg Length B	Wire Size	Drill Ø	Color Code
17634	11mm	15mm	13mm	1.5mm	1.8mm	Green
17635	11mm	17mm	15mm	1.5mm	1.8mm	Green
17636	11mm	19mm	17mm	1.5mm	1.8mm	Green
17626	18mm	18mm	15mm	2.0mm	2.4mm	Yellow



22797 - Memory Staple Gen 2

Location	Item #	Description
1	17647	Anchor pin
2	17653	Large staple punch
3	17654	Small staple punch
4	17652	Large staple clamp
5	17651	Small staple clamp
6	17681	Drill guide adjustable
7	22448	Static drill guide 7-9mm
8	22449	Static drill guide 11-13mm
9	22450	Static drill guide 15-18mm
10	22451	Static drill guide 20-25mm



17707 - Memory Staple Kit

Location	Item #	Description
1	17647	Anchor pin
2	17655	Angled staple punch
3	17653	Large staple punch
4	17654	Small staple punch
5	17652	Large staple clamp
6	17651	Small staple clamp
7	17681	Drill guide adjustable
8	17656	Drill guide single hole
9	17648	Drill guide 7 - 9mm
10	17649	Drill guide 11 - 13mm
11	17650	Drill guide 15 - 18mm
12	17659	Drill bit xsm - 1.4mm
13	17660	Drill bit sm - 1.8mm
14	17661	Drill bit md - 2.4mm
15	17662	Drill bit lg - 3.0mm

Sterile Packaged Drill Bits

Item #	Description
17750	X-Small Drill Bit - 1.4mm Sterile
17751	Small Drill Bit - 1.8mm Sterile
17752	Medium Drill Bit - 2.4mm Sterile
17753	Large Drill Bit - 3.0mm Sterile

Reimbursement

Outpatient Reimbursement (Foot)

CPT Code	Description	National Medicare Average†				
		SI	APC	Hospital Outpatient	PI	Ambulatory Surgical Center
28725	Arthrodesis; subtalar	J1	5115	$12,315	J8	$8,492
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse	J1	5115	$12,315	J8	$9,017
28735	"Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)"	J1	5115	$12,315	J8	$9,169
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	J1	5114	$6,265	J8	$4,404
28750	Arthrodesis, great toe; metatarsophalangeal joint	J1	5114	$6,265	J8	$4,246
28755	Arthrodesis, great toe; interphalangeal joint	J1	5114	$6,265	A2	$2,929
28285	"Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)"	J1	5113	$2,830	A2	$1,328
28297	"Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method"	J1	5114	$6,265	J8	$4,292
28296	"Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method"	J1	5113	$2,830	A2	$1,328
28298	"Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method"	J1	5114	$6,265	J8	$3,794
28300	"Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation"	J1	5114	$6,265	J8	$4,138
28485	"Open treatment of metatarsal fracture, includes internal fixation, when performed, each"	J1	5114	$6,265	J8	$3,947
28505	"Open treatment of fracture, great toe, phalanx or phalanges, includes internal fixation, when performed"	J1	5113	$2,830	A2	$1,328
28525	"Open treatment of fracture, phalanx or phalanges, other than great toe, includes internal fixation, when performed, each"	J1	5113	$2,830	A2	$1,328

Outpatient Reimbursement (Hand)

CPT Code	Description	National Medicare Average				
		SI	APC	Hospital Outpatient	PI	Ambulatory Surgical Center
25820	Arthrodesis, wrist; limited, without bone graft (eg, inter-carpal or radiocarpal)	J1	5114	$6,264	J8	$4,014
25825	Intercarpal fusion; with autograft (includes obtaining graft)	J1	5114	$6,264	J8	$4,014
26850	Arthrodesis, metacarpophalangeal joint, with or without internal fixation	J1	5114	$6,264	A2	$2,929
26841	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation	J1	5114	$6,264	A2	$2,929
26843	Arthrodesis, carpometacarpal joint, digits, other than thumb	J1	5114	$6,264	J8	$3,976
26860	Arthrodesis, interphalangeal joint, with or without internal fixation	J1	5113	$2,830	A2	$1,328

Physician Reimbursement (Foot)		National Medicare Average	
CPT Code	Description	RVU	Payment (Facility)
28725	Arthrodesis; subtalar	22.87	$798
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse;	21.58	$753
28735	“Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)”	22.91	$799
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint	18.12	$632
28750	Arthrodesis, great toe; metatarsophalangeal joint	17.05	$595
28755	Arthrodesis, great toe; interphalangeal joint	9.76	$341
28285	“Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)”	11.13	$388
28297	“Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method”	17.63	$615
28296	“Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method”	14.93	$521
28298	“Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method”	14.61	$510
28300	“Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation”	19.12	$667
28485	“Open treatment of metatarsal fracture, includes internal fixation, when performed, each”	16.45	$574
28505	“Open treatment of fracture, great toe, phalanx or phalanges, includes internal fixation, when performed”	14.55	$508
28525	“Open treatment of fracture, phalanx or phalanges, other than great toe, includes internal fixation, when performed, each”	11.83	$413

Physician Reimbursement (Hand)			
CPT Code	Description	RVU	Payment (Facility)
25820	Arthrodesis, wrist; limited, without bone graft (eg, intercarpal or radiocarpal)	19.13	$667
25825	Intercarpal fusion; with autograft (includes obtaining graft)	23.35	$814
26850	Arthrodesis, metacarpophalangeal joint, with or without internal fixation	21.81	$761
26841	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation	22.92	$799
26843	Arthrodesis, carpometacarpal joint, digits, other than thumb	23.29	$812
26860	Arthrodesis, interphalangeal joint, with or without internal fixation	24.74	$863

†Payment may vary by location. Prices shown are national averages, based on Medicare’s 2021 payments and copayments. Treatments may include one or more procedures.

The coding and reimbursement information and data provided by BioPro, Inc. is presented for informational purposes only and is not a complete listing of possible codes. This reimbursement information does not constitute a representation or guarantee by BioPro, Inc. and BioPro, Inc. will hold no responsibility for the results or consequences of the use of this information.

FDA Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2006

BioPro
% Mr. David Mrak
Director of Product Development
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K061798
Trade/Device Name: Biopro Memory 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: June 21, 2006
Received: June 26, 2006

Dear Mr. Mrak:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Mechus
TDK

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

References

1. Hoon QJ, Pelletier MH, Christou C, Johnson KA, Walsh WR. Biomechanical evaluation of shape-memory alloy staples for internal fixation-an in vitro study. J Exp Orthop. 2016;3(1):19. doi:10.1186/s40634-016-0055-3

2. T.J. Chang and B.D. Overley, “An In Vitro Comparative Study of Screw and Nitinol Staple Compression: A Model Showing Active ‘Dynamic’ Compression,” Presented at the American College of Foot & Ankle Surgeons 65th Annual Scientific Conference, Orlando, FL, March 2007.

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ISO 13485:2016 CERTIFICATION

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