May 3, 2024

Suzhou Endophix Co., Ltd.
Juan Wu
Regulatory Affairs Specialist
No. 151, Fengli Road, SIP
Suzhou, Jiangsu 215000
China

Re: K232941
Trade/Device Name: Megaloop Button System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HTN
Dated: April 3, 2024
Received: April 3, 2024

Dear Juan Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jesse Muir -S Digitally signed by Jesse Muir -S
Date: 2024.05.03 13:44:55 -04'00'

Jesse Muir, Ph.D.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232941

Device Name

Megaloop Button System

Indications for Use *(Describe)*

Megaloop Button System - Megaloop Button with Megaloop Adjustable Loop
The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example, ACL/PCL repair and reconstruction.

Megaloop Button System - Megaloop AD Device
The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example, ACL/PCL repair and reconstruction.

Megaloop Button System - Megaloop FLB Device, Megaloop FLW Device, Megaloop XL Button
Megaloop FLB Device and Megaloop FLW Device are used for fixation of soft tissue to bone in orthopedic procedures such as ACL repair.
When used in conjunction with the Megaloop FLB Device or Megaloop FLW Device, the Megaloop XL Button is intended for fixation of soft tissue to bone in orthopedic procedures such as ACL repairs.

Megaloop Button System - Megaloop DB Device, Megaloop AC Button with Megaloop Adjustable Loop
The Megaloop DB Device and Megaloop AC Button are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.
Specifically:
- The Megaloop DB Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.
- The Megaloop AC Button is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

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.

510(k) Summary

I Submitter

Device submitter: Suzhou Endophix Co., Ltd.
NO.151, Fengli Road, SIP, 215000 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Primary contact person: Juan Wu
Regulatory Affairs Specialist
Phone: +86-17521559984
Email: Juan.Wu@microport.com

Date of preparation: 2023-09-18

II Device

Trade Name of Device:	Megaloop Button System
Common Name:	Titanium Button
Classification Name:	Fastener, Fixation, Non-degradable, Soft Tissue
Regulatory Class:	II
Product Code:	MBI, HTN
Review Panel:	Orthopedic
Regulation Number:	21 CFR 888.3040, 21 CFR 888.3030

III Predicate Devices

Trade Name:	Arthrex PCL Tightrope
Common Name:	Fastener, fixation, nondegradable, soft tissue Suture, Nonabsorbable, synthetic, polyethylene
Classification:	Class II, 21 CFR 888.3040, 21 CFR 878.5000
Product Code:	HTY, GAT
Premarket Notification:	K110123
Manufacturer:	Arthrex, Inc.

Trade Name:	ACL TightRope; ACL TigbtRope Double Bundle
Common Name:	Pin, fixation, smooth Suture, Nonabsorbable,_synthetic,_polyethylene

Classification:	Class II, 21 CFR 888.3040 21 CFR 878.5000
Product Code:	HTY, GAT
Premarket Notification:	K112990
Manufacturer:	Arthrex, Inc.

Trade Name:	RIGIDLOOP Cortical Fixation System
Common Name:	Fastener, Fixation, Soft Tissue
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K130814
Manufacturer:	Medos International SARL, part of DePuy Mitek, Inc.

Trade Name:	RIGIDLOOP™ Titanium Button, RIGIDLOOP™ Cortical Fixation System XL Implant
Common Name:	Fixation Device
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K190774
Manufacturer:	Medos International SARL, part of DePuy Mitek, Inc.

Trade Name:	EndoButton Continous Loop
Common Name:	Suture Retention Device; Surgical Button; Retention Bridge Polyester Surgical Suture
Classification:	Class II, 21 CFR 888.3040, 21 CFR 878.5000
Product Code:	MBI, GAT
Premarket Notification:	K980155
Manufacturer:	Smith & Nephew, Inc., Endoscopy Division

Trade Name:	TightRope™ Syndesmosis Device
Common Name:	Button/Suture
Classification:	Class II, 21 CFR 888.3030
Product Code:	HTN
Premarket Notification:	K043248
Manufacturer:	Arthrex, Inc.

Trade Name:	TightRope™ Acromioclavicular (AC)
Common Name:	Button/Suture
Classification:	Class II, 21 CFR 888.3030

Product Code:	HTN
Premarket Notification:	K052776
Manufacturer:	Arthrex, Inc.

Reference device

Trade Name:	Javelot Ti Suture Anchor, Javelot Ti-D Suture Anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K232725
Manufacturer:	Suzhou Endophix Co., Ltd.

IV Device description

The Megaloop Button System is a family of titanium buttons for the fixation of bone to bone or soft tissue to bone. The system includes a variety of buttons made of Ti-6Al-4V ELI titanium alloy, with or without pre-assembled nonabsorbable loops, sutures and needles. The loops and sutures are offered in non-absorbable Ultra High Molecular Weight Polyethylene (UHMWPE) material. The long straight needles are offered in XM-16 stainless steel material. The sutures and needles are not implantable and are discarded after assisting with button placement.
The Megaloop Button System is provided sterile, non-absorbable, for single use only.

V Indications for use

Megaloop Button System - Megaloop Button with Megaloop Adjustable Loop
The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example, ACL/PCL repair and reconstruction.

Megaloop Button System - Megaloop AD Device
The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example, ACL/PCL repair and reconstruction.

Megaloop Button System - Megaloop FLB Device, Megaloop FLW Device, Megaloop XL Button
Megaloop FLB Device and Megaloop FLW Device are used for fixation of soft tissue to bone in orthopedic procedures such as ACL repair.
When used in conjunction with the Megaloop FLB Device or Megaloop FLW Device, the Megaloop XL Button is intended for fixation of soft tissue to bone in orthopedic procedures such as ACL repairs.

Megaloop Button System - Megaloop DB Device, Megaloop AC Button with Megaloop Adjustable Loop

The Megaloop DB Device and Megaloop AC Button are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically:

- The Megaloop DB Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.
- The Megaloop AC Button is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.

VI Comparison of technological characteristics with the predicate devices

Suzhou Endophix Megaloop Button System has similar technological characteristics and fundamental design as the predicate device. The differences between the subject device and predicate device do not alter suitability of the proposed device for its intended use.

Table 1 Substantial equivalence discussion - Megaloop Button with Megaloop Adjustable Loop

Characteristics	**Subject Device (Megaloop Button with Megaloop Adjustable Loop)**	**Predicate Device K110123**, TightRope ABS Button with TightRope ABS Loop	**Remarks**
Product Code	MBI, HTN	HTY, GAT	Different
Regulation Number	21 CFR 888.3030 21 CFR 888.3040	21 CFR 888.3040 21 CFR 878.5000	Different
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example,	The Arthrex PCL TightRope is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon	Identical as predicate device.

	ACL/PCL repair and reconstruction.	repair. For example, ACL/PCL repair and reconstruction.	
Composition	Button compatible Loop	Button compatible Loop	Identical as predicate device.
Key Patient Contacting Material	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Identical as predicate device.
Button Type	Standard button with two symmetric slots; Round button with two symmetric slots; Oblong button with two slots.	Standard button with two symmetric slots; Round button with two symmetric slots; Oblong button with two slots.	Identical as predicate device.
Dimensional Verification	Standard button: 8 mm × 11 mm, Round button: Φ14mm, Oblong button: 3.4 mm × 13 mm Loop length: adjustable, 170mm	Standard button: 8 mm × 12 mm, Round button: Φ14mm, Oblong button: 3.4 mm × 13 mm Loop length: adjustable, 170mm	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	The loop pass through bone tunnels and allows attachment of the button against the bone cortex.	The loop pass through bone tunnels and allows attachment of the button against the bone cortex.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 2 Substantial equivalence discussion – Megaloop AD Device

Characteristics	**Subject Device (Megaloop AD Device)**	**Predicate Device K112990**, ACL TightRope RT implant	**Remarks**
Product Code	MBI, HTN	HTY, GAT	Different
Regulation Number	21 CFR 888.3030 21 CFR 888.3040	21 CFR 888.3040 21 CFR 878.5000	Different
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	The device is intended to be used for fixation of bone to bone or soft tissue to bone, and is intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. For example, ACL/PCL repair and reconstruction.	The ACL TightRope and ACL TightRope Double Bundle are to be used for fixation of bone to bone or soft tissue to bone, and are intended as fixation posts, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair. Specifically, Arthrex will be offering these for ACL/PCL repair and reconstruction.	Identical as predicate device.
Composition	Implantable part: Button, loop Non-implantable part: Sutures	Implantable part: Button, loop Non-implantable part: Sutures	Identical as predicate device.
Key Patient Contacting Material	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Identical as predicate device.
Button Type	The button is provided with two round holes and one drop type hole	The button is provided with two round holes and one drop type hole	Identical as predicate device.
Dimensional Verification	Button: 3.4mm×13mm Loop length: adjustable, after pretensioning the loop length is 600mm	Button: 3.4mm×13mm Loop length: adjustable, after pretensioning the loop length is 540mm	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization	Identical as

			predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	The loop pass through bone tunnels and allows attachment of the button against the bone cortex. The sutures assist the button passing through tunnels and ensure flipping of the button.	The loop pass through bone tunnels and allows attachment of the button against the bone cortex. The sutures assist the button passing through tunnels and ensure flipping of the button.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 3 Substantial equivalence discussion – Megaloop FLB Device, Megaloop FLW Device, Megaloop XL Button

Characteristics	**Subject Device (Megaloop FLB Device, Megaloop FLW Device, Megaloop XL Button)**	**Predicate Device** **K130814**, RIGIDLOOP™ Fixed Loop (primary predicate) **K980155**, EndoButton CL Ultra **K190774**, RIGIDLOOP™ XL Button (additional predicate)	**Remarks**
Product Code	MBI	MBI (**K130814**) GAT, MBI (**K980155**) MBI (**K190774)**	Identical as predicate device.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040 (**K130814**) 21 CFR 888.3040 21 CFR 878.5000	Identical as predicate device.

		(**K980155**) 21 CFR 888.3040 (**K190774**)	
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	Megaloop FLB Device and Megaloop FLW Device are used for fixation of soft tissue to bone in orthopedic procedures such as ACL repair. When used in conjunction with the Megaloop FLB Device or Megaloop FLW Device, the Megaloop XL Button is intended for fixation of soft tissue to bone in orthopedic procedures such as ACL repairs.	The RIGIDLOOP™ Cortical Fixation System (**K130814**) is used for the fixation of soft tissue to bone in orthopedic procedures such as ACL repair. The EndoButton Continuous Loop (**K980155**) is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction. When used in conjunction with the RIGIDLOOP Cortical Fixation System, the RIGIDLOOP Cortical Fixation System XL Implant (**K190774**) is intended for fixation of soft tissue to bone in orthopedic procedures such as ACL repairs.	Identical as predicate device.
Composition	**Megaloop FLB Device, Megaloop FLW Device** Implantable part: Button, loop	(**K130814, K980155**) Implantable part: Button, loop Non-implantable part:	Identical as predicate device.

	Non-implantable part: Sutures **Megaloop XL Button** Implantable part: Button	Sutures (**K190774**) Implantable part: Button	
Key Patient Contacting Material	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	**K130814** Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE **K980155** Button: Ti-6Al-4V ELI titanium alloy Loop: Polyethylene Terephthalate (PET) **K190774** Button: Ti-6Al-4V ELI titanium alloy	Substantially equivalent.
Button Type	**Megaloop FLB Device, Megaloop FLW Device** The button is provided with four round holes **Megaloop XL Button** The button consists of an elongated titanium plate with a recess and two symmetrical lateral slots	(**K130814, K980155**) The button is provided with four round holes (**K190774**) The button consists of an elongated titanium plate with a recess and two symmetrical lateral slots	Identical as predicate device.
Loop Type	Megaloop FLW Device: weaved loop Megaloop FLB Device: blended loop	K130814: weaved loop K980155: blended loop	Identical as predicate device.
Dimensional Verification	**Megaloop FLB Device, Megaloop FLW Device** Button: 4mm × 12mm Loop length: 15-60mm in 5mm increments	**K130814** Button: 4mm × 12mm Loop length: 15-60mm in 5mm increments **K980155** Button width: from 4 to	Substantially equivalent.

	Megaloop XL Button Button: 5.5mm × 20mm	6mm Button length: from 12 to 18mm Loop length: 10-80 mm **K190774** Button: 5.5mm × 20mm	
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	**Megaloop FLB Device, Megaloop FLW Device** The loop pass through tunnels and allows attachment of the button against the bone cortex. The sutures assist the button passing through tunnels and ensure flipping of the button. **Megaloop XL Button** Pass the Megaloop FLB Device or Megaloop FLW Device through the hole in the Megaloop XL Button from the bottom to provide additional width to the Megaloop FLB Device or Megaloop FLW Device.	(**K130814, K980155**) The loop pass through tunnels and allows attachment of the button against the bone cortex. The sutures assist the button passing through tunnels and ensure flipping of the button. (**K190774**) Pass the Standard Implant through the hole in the XL Implant from the bottom to provide additional width to the Standard Implant.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 4 Substantial equivalence discussion – Megaloop DB Device

Characteristics	**Subject Device (Megaloop DB Device)**	**Predicate Device K043248**, Knotless TightRope™ Syndesmosis Repair Kit	**Remarks**
Product Code	HTN	HTN	Identical as predicate device.
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	The Megaloop DB Device and Megaloop AC Button are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically: - The Megaloop DB Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber	The Arthrex TightRope ™ Syndesmosis Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope™ Syndesmosis Device is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.	Identical as predicate device.

	B and C ankle fractures. - The Megaloop AC Button is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.		
Composition	Implantable part: Button, loop Non-implantable part: Suture, needle	Implantable part: Button, loop Non-implantable part: Suture, needle	Identical as predicate device.
Key Patient Contacting Material	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Button: Ti-6Al-4V ELI titanium alloy Loop: UHMWPE	Identical as predicate device.
Button type	One round button with four round holes, and one oblong button with one round hole and one drop type hole	One round button with four round holes, and one oblong button with one round hole and one drop type hole	Identical as predicate device.
Dimensional Verification	Round button: Φ6.5mm Oblong button: 3.4mm × 13mm Loop length: adjustable, after pretensioning the loop length is 520mm	Round button: Φ6.5mm Oblong button: 3.5mm × 13mm Loop length: adjustable, after pretensioning the loop length is 520mm	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating	The needle and suture	The needle and suture	Identical as

Principle	assist the oblong button to pass through bone tunnels, the round button slides down to the bone by tensioning the loop.	assist the oblong button to pass through bone tunnels, the round button slides down to the bone by tensioning the loop.	predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5 Substantial equivalence discussion – Megaloop AC Button

Characteristics	**Subject Device (Megaloop AC Button)**	**Predicate Device K052776**, Dog Bone™ Button	**Remarks**
Product Code	HTN	HTN	Identical as predicate device.
Regulation Number	21 CFR 888.3030	21 CFR 888.3030	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	The Megaloop DB Device and Megaloop AC Button are intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically: - The Megaloop DB Device is intended to provide fixation during the healing process following	The TightRope ™ Acromioclavicular (AC) Device is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting. Specifically, the Arthrex TightRope Acromioclavicular (AC) Device is intended to	Identical as predicate device.

	a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures. - The Megaloop AC Button is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.	
Composition	Button	Button	Identical as predicate device.
Key Patient Contacting Material	Button: Ti-6Al-4V ELI titanium alloy	Button: Ti-6Al-4V ELI titanium alloy	Identical as predicate device.
Button type	In the shape of a four-leaf clover, with two symmetric slots	In the shape of a four-leaf clover, with two symmetric slots	Identical as predicate device.
Dimensional Verification	Button: 8mm×10mm	Button: 8mm×10mm	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	The loop pass through bone tunnels and allows attachment of the button against the bone cortex.	The loop pass through bone tunnels and allows attachment of the button against the bone cortex.	Identical as predicate device.

Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

VII Performance data

Non-clinical bench tests were conducted in support of the substantial equivalence determination.

Material Standards

The material standards are the essential part to be complied with first, as it is the basis of manufacturing surgical implants.

We have complied with the following material standards:

ISO 5832-3:2021 Implants for surgery - Metallic materials Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

ASTM F2848-17: Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.

Biocompatibility testing

Biocompatibility of the Megaloop Button System was evaluated in accordance with ISO 10993-1: 2018 for the body contact category of “Implant medical device - Tissue/ bone” with a contact duration of “Long term (> 30 d)” and “Externally communicating medical device - Tissue/ bone/ dentin” with a contact duration of “Limited (≤24 h)”.

Bacterial endotoxin testing

Bacterial endotoxins for the implantable components are determined using LAL testing to meet endotoxin limit specifications.

The device is not labeled as non-pyrogenic or pyrogen free.

Mechanical performance testing

The following are the mechanical tests that have been performed on the Subject device (i.e. The Megaloop AD Device) and Predicate device (i.e. Arthrex's ACL TightRope RT implant):

1. Pullout test
2. Fatigue test

Sterilization and Shelf-life testing

The sterilization method has been validated according to ISO 11135 to a SAL of 10^{-6}, which has thereby determined the routine control and monitoring parameters, 5-year shelf-life of the device has been evaluated by accelerated aging test.

VIII Conclusion

The Megaloop Button System is substantially equivalent to the predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.