May 23,2023

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

Re: K230874
Trade/Device Name: Syntheface PEEK Interference Screw, Syntheface PEEK Screw Sheath
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: March 30, 2023
Received: March 30, 2023

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 (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,

Sara S. Thompson -S

For

Yu-Chieh Chiu, Ph.D.
Acting 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.

510(k) Number *(if known)*
K230874

Device Name
Syntheface PEEK Interference Screw

Indications for Use *(Describe)*
The Syntheface PEEK Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9mm or less are also indicated for use in the following procedures:

Knee
-ACL Repair
-PCL Repair
-Extra-capsular repair
  Medial collateral ligament
  Lateral collateral ligament
  Posterior oblique ligament
-Patellar realignment and tendon repair
  Vastus medialis obliquus advancement
-Iliotibial band tenodesis

Shoulder
-Capsular stabilization
  Bankart repair
  Anterior shoulder instability
  SLAP lesion repair
  Capsular shift or capsulolabral reconstruction
-Acromioclavicular separation repair
-Deltoid repair
-Rotator cuff tear repair
-Biceps tenodesis

Foot and Ankle
-Hallux valgus repair
-Medial or lateral instability repair/reconstruction
-Achilles tendon repair/reconstruction
-Midfoot reconstruction
-Metatarsal ligament/tendon repairs/reconstruction
-Bunionectomy
-Flexor Hullucis Longus (FLH)
-Tendon Transfer

Elbow, Wrist, and Hand
-Biceps tendon reattachment
-Ulnar or radial collateral ligament reconstruction
-Lateral epicondylitis repair
-Scapholunate ligament reconstruction
-Tendon Transfer
-Carpometacarpal Joint Arthroplasty

-Carpal Ligament Reconstruction

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.

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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)*
K230874

Device Name
Syntheface PEEK Screw Sheath

Indications for Use *(Describe)*

The Syntheface PEEK Screw Sheath is indicated for use in combination with Syntheface PEEK Interference Screw for fixation of soft tissue to bone during cruciate ligament reconstruction.

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: 2023-03-30

II Device

Trade Name of Device:	Syntheface PEEK Interference Screw, Syntheface PEEK Screw Sheath
Common Name:	Screw, Screw Sheath
Classification Name:	Fastener, Fixation, Non-degradable, Soft Tissue
Regulatory Class:	II
Product Code:	MBI, HWC
Review Panel:	Orthopedic
Regulation Number:	888.3040

III Predicate Devices

Trade Name:	Biosure PK Interference Screw
Common Name:	Screw, Fixation, Bone
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K083635
Manufacturer:	Smith & Nephew Inc., Endoscopy Division

Trade Name:	BIOSURE SYNC Tibial Fixation Device
Common Name:	Screw, Fixation, Bone
Classification:	Class II, 21 CFR 888.3040
Product Code:	HWC, MBI

Premarket Notification:	K093943
Manufacturer:	Smith & Nephew Inc., Endoscopy Division

IV Device description

All Syntheface PEEK Interference Screws are non-absorbable. All interference screws are offered in a polyetheretherketone (PEEK) material. Syntheface PEEK Interference Screws are provided sterile, for single use only.
The Syntheface PEEK Interference Screws are composed of 6 different configurations ranging from 6mm to 11mm in diameter and 25mm in length.
The Syntheface PEEK Interference Screw can be used alone or be used in conjunction with the Syntheface PEEK Screw Sheath.

The Syntheface PEEK Screw Sheath shall be used in conjunction with the Syntheface PEEK Interference Screw. All Syntheface PEEK Screw Sheaths are non-absorbable, and are intra-tunnel devices used to secure soft tissue grafts to bone during cruciate ligament reconstruction procedures. The Syntheface PEEK Screw Sheath is a polyetheretherketone (PEEK) material implant for use with Syntheface PEEK Interference Screw. Syntheface PEEK Screw Sheaths are provided sterile, for single use only.

The models of Syntheface PEEK Interference Screws and Syntheface PEEK Screw Sheath are listed as below:

Trade name	Model
Syntheface PEEK Interference Screw	MS-2025PS-6
	MS-2025PS-7
	MS-2025PS-8
	MS-2025PS-9
	MS-2025PS-10
	MS-2025PS-11
Syntheface PEEK Screw Sheath	MS2025PW-6
	MS2025PW-8
	MS2025PW-10
	MS2025PW-12

V Indications for use

The Syntheface PEEK Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9mm or less are also indicated for use in the following procedures:
Knee

-ACL Repair
-PCL Repair
-Extra-capsular repair
  • Medial collateral ligament
  • Lateral collateral ligament
  • Posterior oblique ligament
-Patellar realignment and tendon repair
  • Vastus medialis obliquus advancement
-Iliotibial band tenodesis

Shoulder
-Capsular stabilization
  • Bankart repair
  • Anterior shoulder instability
  • SLAP lesion repair
  • Capsular shift or capsulolabral reconstruction
-Acromioclavicular separation repair
-Deltoid repair
-Rotator cuff tear repair
-Biceps tenodesis

Foot and Ankle
-Hallux valgus repair
-Medial or lateral instability repair/reconstruction
-Achilles tendon repair/reconstruction
-Midfoot reconstruction
-Metatarsal ligament/tendon repairs/reconstruction
-Bunionectomy
-Flexor Hullucis Longus (FLH)
-Tendon Transfer

Elbow, Wrist, and Hand
-Biceps tendon reattachment
-Ulnar or radial collateral ligament reconstruction
-Lateral epicondylitis repair
-Scapholunate ligament reconstruction
-Tendon Transfer
-Carpometacarpal Joint Arthroplasty
-Carpal Ligament Reconstruction

The Syntheface PEEK Screw Sheath is indicated for use in combination with Syntheface

PEEK Interference Screw for fixation of soft tissue to bone during cruciate ligament reconstruction.

VI Comparison of technological characteristics with the predicate devices

Syntheface PEEK Interference Screws and Syntheface PEEK Screw Sheaths have similar technological characteristics and fundamental design as the predicate devices. The differences between the subject device and predicate device do not alter suitability of the proposed device for its intended use.

Table 5.1 Substantial equivalence discussion -Syntheface PEEK Interference Screw

Characteristics	**Subject Device (Syntheface PEEK Interference Screw)**	**Predicate Device K083635**, Biosure PK Interference Screw	**Remarks**
Product Code	MBI	MBI	Identical as predicate device.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for use	The Syntheface PEEK Interference Screw is indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9mm or less are also indicated for use in the following procedures: **Knee** -ACL Repair -PCL Repair -Extra-capsular repair • Medial collateral ligament	The Smith & Nephew BIOSURE PK Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9mm or less are also intended for use in the following procedures: **Knee** -ACL Repairs -PCL Repairs -Extra-capsular repairs • Medial collateral	Identical as predicate device.

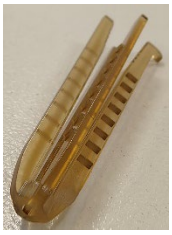
	• Lateral collateral ligament • Posterior oblique ligament -Patellar realignment and tendon repair • Vastus medialis obliquus advancement -Iliotibial band tenodesis **Shoulder** -Capsular stabilization • Bankart repair • Anterior shoulder instability • SLAP lesion repair • Capsular shift or capsulolabral reconstruction -Acromioclavicular separation repair -Deltoid repair -Rotator cuff tear repair -Biceps tenodesis **Foot and Ankle** -Hallux valgus repair -Medial or lateral instability repair/reconstruction -Achilles tendon repair/reconstruction -Midfoot reconstruction -Metatarsal ligament/tendon repairs/reconstruction -Bunionectomy -Flexor Hullucis Longus (FLH) -Tendon Transfer	ligament • Lateral collateral ligament • Posterior oblique ligament -Patellar realignment and tendon repairs • Vastus medialis obliquous advancement -Iliotibial band tenodesis **Shoulder** -Capsular stabilization • Bankart repair • Anterior shoulder instability • SLAP lesion repairs • Capsular shift or capsulolabral reconstructions -Acromioclavicular separation repairs -Deltoid repairs -Rotator cuff tear repairs -Biceps tenodesis **Foot and Ankle** -Hallux valgus repairs -Medial or lateral instability repairs/reconstructions -Achilles tendon repairs/reconstructions -Midfoot reconstructions -Metatarsal ligament/tendon repairs/reconstructions -Bunionectomy -Flexor Hullucis Longus (FLH)	

	Elbow, Wrist, and Hand -Biceps tendon reattachment -Ulnar or radial collateral ligament reconstruction -Lateral epicondylitis repair -Scapholunate ligament reconstruction -Tendon Transfer -Carpometacarpal Joint Arthroplasty -Carpal Ligament Reconstruction	-Tendon Transfers **Elbow, Wrist, and Hand** -Biceps tendon reattachment -Ulnar or radial collateral ligament reconstructions -Lateral epicondylitis repair -Scapholunate ligament reconstruction -Tendon Transfers -Carpometacarpal Joint Arthroplasty -Carpal Ligament Reconstruction	
Picture			Similar as predicate device.
Composition	Interference Screw	Interference Screw	Identical as predicate device.
Patient Contacting Material	PEEK 100% (Optima PEEK)	PEEK 100% (Optima PEEK)	Identical as predicate device.
Dimensional Verification	Interference screw diameter: 6mm, 7mm, 8mm, 9mm, 10mm, 11mm Interference screw length: 25mm	Interference screw diameter: 6mm, 7mm, 8mm, 9mm, 10mm, 11mm Interference screw length: 25mm	Substantially equivalent.
Sterilization	EO sterilization	Irradiation sterilization	Different, but subject device has a SAL of 10^{-6} and EO sterilization

			method had been validated.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	The Syntheface PEEK Interference Screw is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery.	The Biosure PK Interference Screw is a fixation screw that fixes soft tissue such as ligaments, tendons, and the articular capsules to bone, and is used in orthopedic surgery.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5.2 Substantial equivalence discussion -Syntheface PEEK Screw Sheath

Characteristics	**Subject Device (Syntheface PEEK Screw Sheath)**	**Predicate Device K093943**, Biosure SYNC Tibial Fixation Device	**Remarks**
Product Code	HWC, MBI	HWC, MBI	Identical as predicate device.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for use	The Syntheface PEEK Screw Sheath is indicated for use in combination with Syntheface PEEK Interference Screw for	The Smith & Nephew BIOSURE SYNC Tibial Fixation Device is indicated for use in combination with BIOSURE PK Screws for	Identical as predicate device.

<table>
<tr><td></td><td>fixation of soft tissue to bone during cruciate ligament reconstruction.</td><td>fixation of soft tissue to bone during cruciate ligament reconstruction.</td><td></td></tr>
<tr><td>Picture</td><td>  </td><td>  </td><td>Similar as predicate device.</td></tr>
<tr><td>Composition</td><td>Screw Sheath</td><td>Screw Sheath</td><td>Identical as predicate device.</td></tr>
<tr><td>Patient Contacting Material</td><td>PEEK 100% (Optima PEEK)</td><td>PEEK 100% (Optima PEEK)</td><td>Identical as predicate device.</td></tr>
<tr><td>Dimensional Verification</td><td>Screw Sheath width: 9mm, 10.5mm, 12.6mm, 14.6mm;
Screw Sheath height: 10.5mm, 12.2mm, 14.7mm, 17.8mm;
Screw Sheath length: 34mm</td><td>BIOSURE SYNC Device width: 9.6mm, 11.1mm, 13.3mm, 15.3mm;
BIOSURE SYNC Device height: 11mm, 12.5mm, 15.3mm, 18.3mm;
BIOSURE SYNC Device length: 34mm</td><td>Substantially equivalent, and performance bench tests had been conducted to support the substantial equivalence.</td></tr>
<tr><td>Compatible screw size</td><td><table><tr><th>Interference screw (X mm × 25 mm)</th><th>Screw sheath (mm)</th></tr><tr><td>6</td><td>6</td></tr><tr><td>7</td><td>8</td></tr><tr><td>8</td><td>8</td></tr><tr><td>9</td><td>10</td></tr><tr><td>10</td><td>10</td></tr><tr><td>11</td><td>12</td></tr></table></td><td><table><tr><th>BIOSURE PK screw (X mm × 25 mm)</th><th>BIOSURE SYNC Device (mm)</th></tr><tr><td>6</td><td>5-6</td></tr><tr><td>7</td><td>7-8</td></tr><tr><td>8</td><td>7-8</td></tr><tr><td>9</td><td>9-10</td></tr><tr><td>10</td><td>9-10</td></tr><tr><td>11</td><td>11-12</td></tr></table></td><td>Similar as predicate device.</td></tr>
<tr><td>Sterilization</td><td>EO sterilization</td><td>Irradiation sterilization</td><td>Different, but subject device has a</td></tr>
</table>

			SAL of 10^{-6} and EO sterilization method had been validated.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operation principle	Insert the screw sheath into the tibial tunnel. The sheath separates the graft strands and places them against the tunnel wall. Then the screw will be inserted into the center of the screw sheath to achieve the fixation of soft tissue to bone during cruciate ligament reconstruction	Insert the screw sheath into the tibial tunnel. The sheath separates the graft strands and places them against the tunnel wall. Then the screw will be inserted into the center of the screw sheath to achieve the fixation of soft tissue to bone during cruciate ligament reconstruction	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:

ASTM F2026-17: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications

Biocompatibility testing

Biocompatibility of the Syntheface PEEK Interference Screw and Syntheface PEEK Screw Sheath were 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)”.

Bacterial endotoxin testing

Bacterial endotoxins for the interference screw and screw sheath are determined using LAL testing to meet endotoxin limit specifications.

Mechanical performance testing

The following are the mechanical tests that have been performed on the Subject device and Predicate device:

1. Screw-in test
2. Pullout test
3. Fatigue test

Sterilization and Shelf-life testing

The sterilization method has been validated according to ISO 11135:2014 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 ageing test.

Safety in MRI

The Syntheface PEEK Interference Screw and Syntheface PEEK Screw Sheath are MR safe as the polyetheretherketone material is nonmetallic, nonconducting materials that do not contain ferromagnetic materials or any other metallic markers that can interfere with magnetic resonance imaging (MRI). There are no concerns with the performance of the devices in an MRI environment. These devices are labeled MR safe per ASTM F2503.

VIII Conclusion

The Syntheface PEEK Interference Screw and Syntheface PEEK Screw Sheath are substantially equivalent to the predicate devices. The non-clinical testing demonstrates that the devices are as safe, as effective and performs as well as the legally marketed devices.