June 2, 2025

Science & Bio Materials (S.B.M.) SAS
Anne Cospin
Quality & Regulatory Affairs Director
ZI du Monge
Lourdes, 65100
France

Re: K250844
Trade/Device Name: PULLUP®; PULLUP® CLIP; BT LOOP®; PULLUP® TEX CLIP; RIGIDLOOP™ T; RIGIDLOOP™ Clip; RIGIDLOOP™ BTB; RIGIDLOOP™ Suture Loop
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 20, 2025
Received: March 20, 2025

Dear Anne Cospin:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferriera, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250844

Device Name

PULLUP®;
PULLUP® CLIP;
BT LOOP®;
PULLUP® TEX CLIP;
RIGIDLOOP™ T;
RIGIDLOOP™ Clip;
RIGIDLOOP™ BTB;
RIGIDLOOP™ Suture Loop

Indications for Use *(Describe)*

The PULLUP®, BT LOOP®, PULLUP® CLIP and PULLUP® TEX CLIP cortical fixation devices are indicated in adults for reconstruction of the anterior cruciate ligament.
- PULLUP®, PULLUP® CLIP, PULLUP® TEX CLIP must be used with a Soft Tissue Transplant.
- BT LOOP® must be used with a Bone Tendon Bone Transplant.

The RIGIDLOOP™ T, RIGIDLOOP™ BTB, RIGIDLOOP™ Clip and RIGIDLOOP™ Suture Loop cortical fixation devices are indicated in adults for reconstruction of the anterior cruciate ligament.
- RIGIDLOOP™ T, RIGIDLOOP™ Clip, RIGIDLOOP™ Suture Loop must be used with a Soft Tissue Transplant.
- RIGIDLOOP™ BTB must be used with a Bone Tendon Bone Transplant.

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) #: K250844

510(k) Summary

Prepared on: 2025-05-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Science & Bio Materials (S.B.M.) SAS
Applicant Address	ZI du Monge Lourdes 65100 France
Applicant Contact Telephone	33562422101
Applicant Contact	Mrs. Anne COSPIN
Applicant Contact Email	anne.cospin@sbm-fr.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PULLUP®; PULLUP® CLIP; BT LOOP®; RIGIDLOOP™ T; RIGIDLOOP™ Clip; RIGIDLOOP™ BTB; PULLUP® TEX CLIP; RIGIDLOOP™ Suture Loop
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number	888.3040
Product Code(s)	MBI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202193	PULLUP® BTB / PULLUP® CLIP / PULLUP® TEX CLIP / BT LO	MBI
K151004	PULLUP®	MBI

Device Description Summary

21 CFR 807.92(a)(4)

- PULLUP®: comprises a titanium button-plate, and an adjustable nonabsorbable braided loop. The system is preloaded with traction and flip threads, and is designed to be used with a soft tissue graft. Standard and XL sizes.
- BT LOOP®: comprises a titanium button-plate, and an adjustable nonabsorbable braided loop. The system is preloaded with traction and flip threads, as well as a temporary splice suture, and is designed to be used with a bone-tendon-bone graft. It is assembled on a holder that can be mounted on the GraftTech® preparation station. Standard and XL sizes.
- PULLUP® CLIP: comprises a titanium button-plate only, is designed to be used with a soft tissue graft, and can either be connected to another CLIP button-plate by using the PULLUP® TEX CLIP nonabsorbable braided loop, or can be connected to another PULLUP® device. Standard and XL sizes.
- PULLUP® TEX CLIP: Comprises a nonabsorbable braided loop. One size only.

Standard models are used for cortical tunnels with a diameter of 4.5 mm; XL models are used for cortical tunnels with a diameter between 5 and 10 mm.

The implants are supplied sterile, individually packaged, ready to use.

The PULLUP®, PULLUP® CLIP, BT LOOP® and PULLUP® TEX CLIP devices are also sold under the trade names RIGIDLOOP™ T, RIGIDLOOP™ Clip, RIGIDLOOP™ BTB and RIGIDLOOP™ Suture Loop respectively.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PULLUP®, BT LOOP®, PULLUP® CLIP and PULLUP® TEX CLIP cortical fixation devices are indicated in adults for reconstruction of the anterior cruciate ligament.
- PULLUP®, PULLUP® CLIP, PULLUP® TEX CLIP must be used with a Soft Tissue Transplant.
- BT LOOP® must be used with a Bone Tendon Bone Transplant.

The RIGIDLOOP™ T, RIGIDLOOP™ BTB, RIGIDLOOP™ Clip and RIGIDLOOP™ Suture Loop cortical fixation devices are indicated in adults for reconstruction of the anterior cruciate ligament.
- RIGIDLOOP™ T, RIGIDLOOP™ Clip, RIGIDLOOP™ Suture Loop must be used with a Soft Tissue Transplant.
- RIGIDLOOP™ BTB must be used with a Bone Tendon Bone Transplant.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same as those of the legally marketed devices K202193.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate device and subject device are substantially equivalent in terms of intended use, material, design, mechanical properties and function. Minor differences do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function, or intended use of this device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

• Ultimate failure load (post-fatigue tensile strength) and fatigue displacement met the acceptance criteria established by the predicate device (K202193).
• Biocompatibility testing per ISO 10993-1:2018 demonstrated passing results.
• Bacterial endotoxin testing was completed and met acceptable limits per ISO 11737-3 (2023)
• The devices have a five (5) year shelf-life. Storage and stability is based on completed packaging material storage stability testing, device storage stability testing, and distribution testing. Packaging testing per ISO 11607-1:2019 demonstrated passing results.
• Sterile adoption was completed per ISO 11137-1:2006
• MRI safety was evaluated according to ASTM F2503 - 20, IEC 62570:2014 and FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment

Not Applicable

There is no change in material, intended use, indications for use, sterilization method, and shelf-life.
Changes in design are minor, and do not raise new or different questions of safety
and effectiveness compared with the predicate device. The non-clinical testing has demonstrated that the PULLUP®/BT LOOP®/ RIGIDLOOP™ subject devices are substantially equivalent to their PULLUP®/BT LOOP®/RIGIDLOOP™ predicate devices.