October 16, 2020

S.B.M. SAS (Science & Bio Materials)
Anne Cospin-Latapie
Quality/Regulatory Affairs Manager
Zi Du Monge
Lourdes, 65100
France

Re: K202193
Trade/Device Name: PULLUP® BTB Adjustable Fixation System for Ligament Reconstruction,
PULLUP® CLIP Adjustable Fixation System for Ligament Reconstruction,
PULLUP® TEX CLIP Adjustable Fixation System for Ligament Reconstruction,
BT LOOP® Adjustable Fixation System for Ligament Reconstruction
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 30, 2020
Received: August 5, 2020

Dear Anne Cospin-Latapie:

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,

for

Laura C. Rose, 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

FORM 3881

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)*
K202193

Device Name
PULLUP® BTB Adjustable fixation system for ligament reconstruction, PULLUP® CLIP Adjustable fixation system for ligament reconstruction, PULLUP® TEX CLIP Adjustable fixation system for ligament reconstruction and BT LOOP® Adjustable fixation system for ligament reconstruction.

Indications for Use *(Describe)*
The PULLUP® BTB, BT LOOP®, PULLUP® CLIP and PULLUP® TEX CLIP devices are designed to be used as cortical fixation for ACL 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. SUBMITTER

S.B.M. SAS SCIENCE & BIO MATERIALS ZI du Monge F 65100 LOURDES – FRANCE Registration Number: 3004549189
Phone: +33 (0)5 62 42 21 01 Fax: +33 (0)5 62 42 21 00
Contact Person: Anne COSPIN-LATAPIE e-mail : anne.cospin@sbm-fr.com
Date prepared: 03 July 2020

2. DEVICE

Name of Device	PULLUP® BTB, BT LOOP®, PULLUP® CLIP & PULLUP® TEX CLIP
Common or Usual Name	Adjustable Fixation System for Ligament Reconstruction
Classification Name	Fastener, fixation, nondegradable, soft tissue
Regulatory Class	II
Product Code	MBI

3. PREDICATE DEVICE

K151004 - PULLUP® Adjustable Juxtacortical Fixation Device

Referenced devices :

K092533 - FORCE FIBER® BLUE ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE NON ABSORBABLE SUTURES

K930739 - DEKNATEL® SUTURES POLYPROP., POLYETHELINE *(sic)*, NYLON & SILK

4. DEVICE DESCRIPTION

The device is proposed in the following variants:

- **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.
- **PULLUP® BTB**: 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.
- **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 must be mounted on the GraftTech® preparation station.
- **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 **PULLUP® CLIP** button-plate by using the **PULLUP® TEX CLIP** nonabsorbable braided loop, or can be connected to another **PULLUP®** device.

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.

5. INDICATIONS FOR USE

The PULLUP® BTB, BT LOOP®, PULLUP® CLIP & PULLUP® TEX CLIP devices are designed to be used as cortical fixation for ACL reconstruction.

6. PERFORMANCE DATA

Non-clinical performance testing

Non-clinical testing including biocompatibility, biological and mechanical performances were not impacted by the change. The results indicated that the devices were functional within their intended use and equivalent to the predicate devices.

The proposed device has been determined to be non-pyrogenic.

Clinical performance testing:

Clinical performance data was not included.

7. SUBSTANTIAL EQUIVALENCE

The modifications to the PULLUP® Adjustable cortical fixation device (K151004) consist in the addition of new variants for ACL reconstruction: two systems for ACL reconstruction with a bone-tendon-bone graft, one of which must be used with SBM's GraftTech® preparation station, and a system for ACL reconstruction with a connectable button-plate that can be attached to other PULLUP® systems.

The added systems are substantially equivalent to their predicate device PULLUP® (K151004) in terms of intended use, material, design, mechanical properties and function.