DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SBM Sciences for Bio Materials
Mr. Denis Clement
CEO
Zi Du Monge
65100 Lourdes
France

November 17, 2015

Re: K151004
Trade/Device Name: PULLUP® Adjustable Juxtacortical Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 15, 2015
Received: October 15, 2015

Dear Mr. Clement:

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Traditional 510(k)
PULLUP® Adjustable Juxtacortical Fixation System

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151004

Device Name
PULLUP® Adjustable Juxtacortical Fixation Device

Indications for Use *(Describe)*
The PULLUP® device is designed to be used as juxtacortical 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.

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Traditional 510(k)
PULLUP® Adjustable Juxtacortical Fixation System

SECTION 5

510(k) SUMMARY

1. GENERAL INFORMATION

Type of 510(k)	TRADITIONAL
Trade Name	PULLUP® Adjustable Juxtacortical Fixation Device
CFR section	21CFR 888.3040
Classification Name	Fastener, fixation, nondegradable, soft tissue
Device panel	ORTHOPEDIC
Product Code	MBI
Class	II
Legally marketed predicate devices	K112990 TightRope RT manufactured by Arthrex, Inc. K130033 ToggleLoc System manufactured by Biomet Manufacturing Corp.
Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Registration Number : 3004549189
Contact	Denis CLEMENT, CEO Tel : +33 (0)5 62 42 21 01 Fax : +33 (0)5 62 42 21 00 e-mail : denis.clement@sbm-fr.com Regulatory contact : Anne COSPIN-LATAPIE e-mail : anne.cospin@sbm-fr.com

2. DEVICE DESCRIPTION

The PULLUP® Adjustable Juxtacortical Fixation Device consists of an adjustable nonabsorbable braided loop and titanium button. The system is preloaded with traction threads.

The PULLUP® Adjustable Juxtacortical Fixation Device is available in 2 versions:

- PULLUP® for cortical tunnels having a diameter of 4.5 mm
- PULLUP®XL for cortical tunnels having a diameter between 5 and 10 mm

The implant is supplied sterile, ready to use.

3. INDICATIONS FOR USE

The PULLUP® device is designed to be used as juxtacortical fixation for ACL reconstruction.

4. PERFORMANCE DATA

Non clinical performance testing demonstrated that PULLUP® device is as safe, as effective, and performs at least as safely and effectively as its predicate devices. No clinical data has been presented.

5. SUBSTANTIAL EQUIVALENCE

The PULLUP® device is substantially equivalent to its predicate devices Arthrex TightRope RT (K112990) and Biomet ToggleLoc (K130033). Verification and validation tests demonstrate that the PULLUP® device is as safe, as effective, and performs as safely and effectively as its predicate device.

Summary preparation date: October 20, 2015