January 9, 2019

Cousin Biotech S.A.S.
Franck Pelletier
Regulatory Affairs Director
8 Rue De L'abbe Bonpain
Wervicq-Sud, 59117 France

Re: K181086
Trade/Device Name: Cortical Fixation Systems
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, GAT
Dated: December 11, 2018
Received: December 12, 2018

Dear Mr. Pelletier:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181086

Device Name
Cortical Fixation Systems

Indications for Use *(Describe)*

The Cortical Fixation Systems are used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as anterior cruciate ligament (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.

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510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Submission Date:	April 23, 2018
Submitter:	Cousin Biotech S.A.S. 8 Rue De L'abbe Bonpain 59117 Wervicq-Sud, France
Submitter Contact:	Ms. Mathilde Collet Regulatory Affairs Engineer Phone: +011 33 (3) 20144130 Email: m.collet@cousin-biotech.com
Application Correspondent:	Mr. Franck Pelletier Regulatory Affairs Director Phone: +011 33 (3) 20144119 Email: f.pelletier@cousin-biotech.com
Manufacturing Site:	Cousin Biotech S.A.S. Allée des roses F-59117 Wervicq-Sud, France
Model Name:	Cortical Fixation System Adjustable Cortical Fixation System Extended Plate for Cortical Fixation Systems
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Regulation:	21 CFR §888.3040 21 CFR §878.5000
Product Code:	MBI GAT
Substantially Equivalent Devices:	K980155 – Smith & Nephew, Inc. – EndoButton CL Ultra (Primary) K100652 – Arthrex, Inc. – ACL TightRope (Additional) K083070 – Biomet Sports Medicine – ToggleLoc™ System (Additional)

510(k) Summary

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Device Description: The Cortical Fixation Systems are available in two (2) models. The first one is the Cortical Fixation System (cortical button with fixed length loop). The second model is the Adjustable Cortical Fixation System (cortical button with adjustable length loop). These devices can be used with an Extended Plate which allows a larger surface of contact with the cortical bone. These products are anchor devices with titanium cortical button and are intended to be used as a soft tissue to bone fixation, especially for the ACL repair. The graft is passed through the loop and the titanium button ensures the tensioning and the fixation of the system.

Intended Use: The Cortical Fixation Systems are used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as anterior cruciate ligament (ACL) reconstruction.

Technology Comparison: The Cousin Biotech's Cortical Fixation Systems employ the same technological characteristics as the primary predicate device.

Characteristic	***Smith & Nephew, Incorporated / EndoButton CL Ultra (K980155)***	***Cousin Biotech S.A.S. Cortical Fixation Systems (Proposed Device)***
Design	Titanium button with loop in PET preloaded with two (2) polyester braids sutures (1 green, 1 white)	Titanium button with loop in PET preloaded with two (2) polyester braids sutures (1 green, 1 white)
Sizes	EndoButton: width: 4 – 6 mm length: 12 – 18 mm Suture loop span length: 10 – 80 mm	The titanium button size is 4 mm (width) x 12 mm (length) x 1.5 mm (height). The extended plate size is 7 mm (width) x 20 mm (length) x 1.5 mm (height). The non-adjustable loop size is available from 15 mm to 40 mm. The adjustable loop size is capable of provided a loop from 15 mm to 40 mm. Any size is possible between both values.
Button	Ti-6Al-4V or Ti-6Al-4V ELI titanium alloy.	Ti-6Al-4V or Ti-6Al-4V ELI titanium alloy.
Loop	Polyethylene Terephthalate (PET)	Polyethylene Terephthalate (PET) for the non-adjustable loop Polyethylene (UHMWPE) for the adjustable loop
Traction threads	Polyester (PET)	Polyester (PET) and colorant D&C Green
Shipped Sterile	Yes	Yes

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Summary of Performance Testing:

Sterilization

The Cortical Fixation System and Extended Plate are gamma radiation sterilized and were validated to a sterility assurance level of 10^{-6} in accordance with the following standards:

- *ISO 11137-1: 2006, Am1: 2013, Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization;*
- *ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose;*
- *ISO 11737-1: 2006, Cor1: 2007, Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products [Including: Technical Corrigendum 1 (2007)]; and*
- *ISO 11737-2: 2009, Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*

Validation results indicate that the Cortical Fixation System and Extended Plate comply with the standards.

The Adjustable Cortical Fixation System is Ethylene Oxide sterilized and was validated in accordance with the following standard:

- *ISO 11135:2014, Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices; and*
- *ISO 10993-7: 2008, Cor1: 2009, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]*.

Validation results indicate that the Adjustable Cortical Fixation System complies with the standards.

The Cortical Fixation System, Adjustable Cortical Fixation System, and Extended Plate were tested for pyrogenicity as recommended by the following FDA guidance document:

- *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, 21 Jan 16.*

Validation results indicate that the Cortical Fixation System, Adjustable Cortical Fixation System, and Extended Plate are non-pyrogenic in accordance with the FDA guidance document.

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Shelf Life

The packaging for the Cortical Fixation Systems was validated in accordance with the following standards:

- *ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems;*
- *ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes;*
- *ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems;*
- *ASTM F1929-12, Standard Test Method for Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration; and*
- *ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

Validation results indicate that the packaging for the Cortical Fixation Systems complies with the standards.

Biocompatibility

The Cortical Fixation Systems patient contact materials was verified in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicated that the Cortical Fixation Systems patient contact materials comply with the standard.

Performance Testing – Bench

The Cortical Fixation Systems were tested for performance in accordance with its predetermined specifications and the following standards:

- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices;*
- *ISO 5832-3: 2016, Implants for surgery – Metallic materials – Part 3: Wrought titanium-6 aluminum-4 vanadium alloy; and*
- *ISO 14630: 2012, Non-active surgical implants – General requirements.*

Test results indicate that the Cortical Fixation Systems comply with its predetermined specifications and with the standards.

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of Cortical Fixation System, Adjustable Cortical Fixation System and Extended Plate. The results of these activities demonstrate that the Cortical Fixation Systems are as safe, as effective, and perform as well as or better than the predicate devices.

Therefore, the Cortical Fixation Systems are considered substantially equivalent to the predicate devices.