August 29, 2018

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

Re: K181799
Trade/Device Name: ResCUBE™ Ligament Fixation System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: June 29, 2018
Received: July 5, 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,

Ronald P. Jean -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)*
K181799

Device Name
ResCUBE™ Ligament Fixation System

Indications for Use *(Describe)*
The ResCUBE System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, that can be treated with sublaminar, interspinous or facet wiring techniques.
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis and spondylolisthesis.
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

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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510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Submission Date:	June 29, 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
Trade Name:	ResCUBE™ Ligament Fixation System
Classification Name:	Bone Fixation Cerclage, Sublaminar
Classification Regulation:	21 CFR §888.3010 – Bone Fixation Cerclage, Class II
Product Code:	OWI
Substantially Equivalent Devices:	K172206 – Cousin Biotech S.A.S. - NAJA™ Ligament Correction System (Primary) K922952, K941213 - Pioneer Surgical (now RTI Surgical) - Songer Spinal Cable (Additional Predicate) K153348 - Implanet S.A. - JAZZ LOCK (Additional Predicate)
Device Description:	The ResCUBE™ Ligament Fixation System (ResCUBE System) is a temporary spinal implant intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The ResCUBE System consists of the following components: a ligament allowing correction and stabilization of the levels, after tensioning; a malleable leader allowing guidance of the ligament during surgery and attached to the ligament by a PET sheath; and a low-profile connector holding the tension on the ligament.

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Intended Use:

The ResCUBE System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, that can be treated with sublaminar, interspinous or facet wiring techniques.

2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis and spondylolisthesis.

3. Spinal degenerative surgery, as an adjunct to spinal fusions.

Technology Comparison:

The ResCUBE System employs the same technological characteristics as the primary predicate device.

Characteristic	***Cousin Biotech S.A.S. / NAJA™ Ligament Correction System (K172206)***	***Cousin Biotech S.A.S. / ResCUBE™ Ligament Fixation System (Proposed Device)***
Implant Components	Connector (with lateral hooks) with screw. Ligament with metal guide and PET sheath, but no buckle. (Ligament has a stiff section on one end for guiding the band through the spine.)	Connector (without lateral hooks) with screw. Ligament with metal guide and PET sheath, but no buckle. (Ligament has a stiff section on one end for guiding the band through the spine.)
Sizes	Titanium alloy connector is available in two (2) sizes of 5.5 and 6.0 mm compatible with the same diameter rod constructs.	Titanium alloy connector is available in one (1) size because it is not used with rods. The body of the ResCUBE connector is identical to the NAJA connector less the lateral hooks.
Metal Clamp and Screw (Connector)	TA6V ELI titanium alloy (ASTM F136 and ISO 5832-3).	TA6V ELI titanium alloy (ASTM F136 and ISO 5832-3).
Guide	304L stainless steel. PET sheath.	304L stainless steel. PET sheath.
Shipped Sterile	Yes	Yes

510(k) Summary

provided in accordance with 21 CFR §807.92(C)

Summary of Performance Testing:

Performance Testing – Bench	Static and dynamic tension testing were performed on ResCUBE System. The ResCUBE System was 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; and* • *ISO 14630: 2012, Non-active surgical implants – General requirements.* Test results indicate that the ResCUBE System complies with its predetermined specifications and with the standards.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of ResCUBE System. The results of these activities demonstrate that ResCUBE System is as safe, as effective, and perform as well as or better than the predicate devices. Therefore, the ResCUBE System is considered substantially equivalent to the predicate devices.