April 10, 2018

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

Re: K172206
Trade/Device Name: NAJA™ Ligament Correction System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: March 6, 2018
Received: March 9, 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. 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K172206

Device Name
NAJA™ Ligament Correction System

Indications for Use *(Describe)*
The NAJA 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, used in sublaminar or facet wiring techniques.
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis.
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The NAJA System may also be used in conjunction with other medical grade implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of the other implants.

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)

Date Prepared:	April 9, 2018
Submitter:	Cousin Biotech S.A.S. 8 Rue De L'abbe Bonpain 59117 Wervicq-Sud, France
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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:	NAJA™ Ligament Correction System
Common Name:	Bone Fixation Cerclage, Sublaminar
Classification Regulation:	21 CFR §888.3010 - Bone Fixation Cerclage, Class II
Product Code:	OWI
Predicate Devices:	K110348 - Zimmer Spine - Universal Clamp Spinal Fixation System (Primary) K922952 - Pioneer Surgical Technology - Songer Cable System (Additional)
Device Description:	The NAJA™ Ligament Correction System (NAJA System) is a temporary 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 NAJA implant consists of a titanium alloy connector and a polyethylene terephthalate (PET) woven band. The NAJA System allows the spine to be secured to a rod construct without the use of a bone screw, and acts as an alternative to sublaminar wires and hooks.

Intended Use:

The NAJA 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, used in sublaminar or facet wiring techniques.

2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and spondylolisthesis.

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

The NAJA System may also be used in conjunction with other medical grade implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of the other implants.

Technology Comparison:

The NAJA System is substantially equivalent to the predicates identified in terms of intended use/indications for use, technological characteristics, device materials and function.

Summary of Performance Testing:

Sterilization

The NAJA System is gamma radiation sterilized and was 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; and*
- *ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

Validation results indicate that the NAJA System complies with the standards.

Shelf Life

The packaging for the NAJA System 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; and*
- *ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

Validation results indicate that the packaging for the NAJA System complies with the standards.

Biocompatibility

NAJA System patient contact materials were 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 NAJA System patient contact materials comply with the standard.

Performance Testing – Bench

The following mechanical tests were performed on the NAJA System:

- *Static and dynamic band tension testing*
- *Static axial grip and static torsional grip testing per ASTM F1798-13*
- *Dynamic axial compression testing per ASTM F1717-15*

Test results demonstrate that the NAJA System has substantially equivalent mechanical performance as compared to the predicates listed.

Conclusion

Verification and validation activities were conducted to establish the performance of NAJA System. The results of these activities demonstrate that NAJA System is as safe and as effective as the predicate devices.

Therefore, the NAJA System is considered substantially equivalent to the predicate devices.