April 22, 2022

CoNextions Medical
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K203855
Trade/Device Name: CoNextions TR Tendon Repair System
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless Steel Suture
Regulatory Class: Class II
Product Code: GAQ
Dated: October 12, 2021
Received: October 12, 2021

Dear Janice Hogan:

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,

Kimberly Ferlin -S

for Deborah Fellhauer, RN, BSN
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) SUMMARY
K203855
CoNextions Medical CoNextions TR Tendon Repair System

Applicant Information

Manufacturer: CoNextions Medical
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Salt Lake City, Utah 84116
Ph: 385.351.1461
F: 801.436.5369

Contact Person: Matthew Swift, Director of Clinical Research

Date Prepared: March 18, 2022

Device Information

Name of Device: CoNextions TR Tendon Repair System

Common Name: Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Classification Name: Stainless Steel Suture

Regulatory Class: Class II

Product Code: GAQ

Predicate Devices: K023594, Teno Fix™ Tendon Repair System, Ortheon Medical, LLC. (Primary)
K946173, PROLENE™ Polypropylene Nonabsorble Suture, Ethicon, Inc.

Reference Devices: K041553, Arthrex Fiberwire, Arthrex, Inc.
K930591, TiCron™ Suture, Tyco Healthcare Group LP
K946173, ETHIBOND® Suture, Ethicon, Inc.

Device Description

The CoNextions TR Tendon Repair System consists of a single-use, sterile implant consisting of two identical stainless steel anchors implanted in either end of the injured tendon and connected by two loops of UHMWPE fiber. The implant is provided pre-loaded into an Implant Mechanism and with a Deployment Mechanism to facilitate placement.

Indications for Use

CoNextions TR is intended for the repair of lacerated or severed tendons in adults (22 years of age or older). The product is intended for the following indications:

- Digital Flexor Tendons
- Digital Extensor Tendons Proximal to the Metacarpophalangeal Joint (Zones 6-8)

Summary of Technological Characteristics

Anchoring components are placed in the two lacerated tendon ends and securely connected together and represent the essential technological principles for both the subject and predicate devices. At a high level, the subject and predicate devices are based on the following same technological elements:

- **Anchor Components:** Portion of implant intended to fixate into lacerated tendon ends;
- **Connection:** Portion of implant that secures the two anchoring com ponents togetherand bridges the repair site.

The following technological differences exist between the subject and predicate devices:

- Different form factor for anchoring components;
- Different delivery method for implantation.

Benchtop, animal, and clinical testing, including comparative testing to nonabsorbable polymer sutures, demonstrate the CoNextions TR is substantially equivalent and introduces no new or different questions of safety and effectiveness.

Nonclinical/Bench Performance Data

The following nonclinical/bench testing was conducted for CoNextions TR Implant System.

Testing Category	**Specific Tests Performed**
Performance Testing	Deployment Reliability Static Tensile Testing Cyclic Tensile Testing Glide Evaluation Testing Implant Extraction Testing
Biocompatibility Testing	Toxicologic Risk Assessment Cytotoxicity Sensitization Irritation Pyrogenicity Testing Acute Toxicity Subacute Toxicity Subchronic Toxicity Intramuscular implantation Genotoxicity

Testing Category	Specific Tests Performed
Sterilization Validation	Sterilization Validation EO residual testing Endotoxin (LAL) validation
MR Compatibility	Induced Displacement Testing Induced Torque Testing Induced Heating Testing Image Artifact Testing
Packaging	Package Integrity Testing Accelerated Aging Testing
Animal Testing	Two-week Canine Study Twelve-week Ovine Study

Summary of Clinical Information

Study Overview: A clinical evaluation was conducted at 4 sites with 5 fellowship-trained hand surgeons in order to compare the safety and effectiveness of the CoNextions TR System to a standard of care suture repair method (4-strand locked cruciate repair using PROLENE suture) for the repair of lacerations of the flexor digitorum profundus (FDP) tendon in Zone 2. Participants were randomized intraoperatively following confirmation of meeting all of the inclusion criteria. A standardized rehabilitation protocol was implemented during the first 12 weeks post-procedure. The participants and therapists performing the majority of the outcome assessments were blinded to the assigned treatment arm for the 12 weeks post-procedure with the final follow-up occurring 24 weeks post-procedure.

Ninety (90) participants were screened, met the study enrollment criteria (**Table 1**), and were randomized in to the study with 40 (40/90, 44.4%) participants randomized to the CoNextions TR group and 50 (50/90, 55.6%) participants randomized to the suture group. 8 participants were excluded from the final analysis as they were less than 22 years of age at the time of enrollment and an additional participant was excluded after suffering an injury to their affected limb unrelated to the study that could have impacted the outcome assessments. Of the remaining 81 participants, 72 (72/81, 88.9%) of them provided outcome data at the 12 week follow-up visit and 70 (70/81, 86.4%)) of them provided outcome data at the 24 week follow-up visit.

Table 1. Enrollment Criteria for Clinical Evaluation of CoNextions TR Tendon Repair System

Inclusion Criteria	Exclusion Criteria
1. At least 18 years of age 2. Willing and able to provide a signed and dated informed consent form. 3. Stated willingness to comply with all study procedures 4. Available for the duration of the study 5. Have one or two fully lacerated digital FDP tendon(s), with or without a concomitant injury of the flexor digitorum superficialis, in Zone 2 of the index, middle, ring, or small finger 6. Tendon laceration occurred within the previous 14 days	1. Pregnant or planning to become pregnant during the follow-up period 2. Autoimmune disorder(s) 3. Type 1 diabetes mellitus or clinical history of poorly controlled Type 2 diabetes mellitus 4. Lack of proper cutaneous coverage at repair site 5. Concomitant fracture 6. Amputated digit(s) 7. Arthritis of the hand 8. Prior hand trauma with residual impact to function 9. Congenital hand defect 10. Conditions that would affect comparative measurements in the uninjured hand 11. Tendon laceration caused by a crush injury 12. Prior sensory impairment in digits of either hand. Note: Participants with nerve injuries associated with the trauma causing the current flexor tendon injury are eligible for enrollment 13. Vascular injuries that require revascularisation procedures 14. Ischemia and/or blood supply compromise 15. Prior or current infections at or near the tended implant site

Inclusion Criteria	Exclusion Criteria
	16. Active sepsis, MRSA, or other conditions that may prevent healing 17. History of foreign-body sensitivity to 316 L Stainless Steel or UHMWPE 18. Implantation of CoNextions TR Implant would result in physical contact with other metal implants made of material other than implant grade stainless steel such as titanium, titanium alloys, cobalt chromium, or other dissimilar metals 19. Any condition(s) which, in the opinion of the investigator, may impact the participant's ability to properly follow-up or otherwise be at-risk for following protocol instructions 20. Currently participating in another clinical/device trial 21. Surgical site access less than 20 mm in total or less than 10 mm on either side of the intended implant site 22. Injured tendon outside of the width range (3.0-7.0 mm) and thickness range (1.5-4.0 mm) specified for the CoNextions TR Tendon Repair System

Primary Safety Outcome: The primary safety endpoint of the study was the incidence of re-rupture of the repaired Zone 2 FDP tendon laceration. Repaired digits were evaluated at all post-procedure follow-up visits for signs and symptoms of rupture of the repair. The target safety criterion was a rate of re-rupture of 8% or less at the 12 week follow-up visit. At the 12 week follow-up visit, 1 of 33 (3.0%) participants in the CoNextions TR group experienced a rupture with 5 of 45 (11.1%) participants in the Suture group experiencing a rupture. For all study participants, 1 of 34 (2.9%) participants in the CoNextions TR group and 5 of 47 (10.6%) participants in the Suture group who experienced a rupture.

Secondary Safety Outcomes: Surgical site infection was assessed at all follow-up visits as a secondary safety outcome. For the study participants who experienced a surgical site infection and/or completed the 24 week follow-up visit, one (1) of 34 (2.9%) participants in the CoNextions TR group experienced a surgical site infection with 4 of 47 (8.5%) participants in the Suture group experiencing a surgical site infection. Twenty-six (26) of 34 (76.5%) participants in the CoNextions TR group and 37 of 47 (78.7%) participants in the Suture group experienced at least one adverse event Four (4) of 34 (11.8%) participants in the CoNextions TR group and 7 of 47 (14.9%) participants in the Suture group experienced a serious adverse event. No statistically significant differences were seen between the two groups for these safety outcomes (**Table 2**).

Table 2. Safety Outcomes for the Clinical Evaluation

Safety Outcome	CoNextions TR	Suture
Rupture of Repair	1/34 (2.9%)	5/47 (10.6%)
Surgical Site Infection	1/34 (2.9%)	4/47 (8.5%)
At Least One Adverse Event	26/34 (76.5%)	37/47 (78.7%)
At least One Serious Adverse Event	4/34 (11.8%)	7/47 (14.9%)

Notes: All values are presented as Participants with Safety Outcome/Total Participants, %.

Adverse Events: There were 155 total adverse events (AE) in the CoNextions TR group with 29 (18.7%) of them not affecting or related to the injured digit(s). A listing of all adverse events related to the injured digit(s) for both study groups is shown in **Table 3**.

Table 3. Adverse Events Affecting the Injured Digit(s)

Adverse Event		CoNextions TR	Suture
Pain	Participants with AE (Y/N, %)	14/34 (41.2%)	21/47 (44.7%)
	Total number AE	44	52
Stiffness	Participants with AE (Y/N, %)	16/34 (47.1%)	21/47 (44.7%)

Adverse Event		CoNextions TR	Suture
	Total number AE	28	31
Swelling	Participants with AE (Y/N, %)	13/34 (38.2%)	21/47 (44.7%)
	Total number AE	24	34
Neuralgia	Participants with AE (Y/N, %)	10/34 (29.4%)	16/47 (34.0%)
	Total number AE	18	21
Adhesion	Participants with AE (Y/N, %)	2/34 (5.9%)	2/47 (4.3%)
	Total number AE	2	2
Rupture of Repair	Participants with AE (Y/N, %)	1/34 (2.9%)	5/47 (10.6%)
	Total number AE	1	6
Septic Surgical Site Infection	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2.1%)
	Total number AE	2	1
Scarring of Surgical Incision	Participants with AE (Y/N, %)	1/34 (2.9%)	4/47 (8.5%)
	Total number AE	1	4
Flexion Deformity/Contracture	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2,1%)
	Total number AE	1	1
Delayed Healing of Incision	Participants with AE (Y/N, %)	1/34 (2.9%)	2/47 (4.3%)
	Total number AE	1	2
Hyperextension of Repaired Digit	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Device Positioned Incorrectly During Surgery	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Other AE not seen in CoNextions TR Group	Participants with AE (Y/N, %)	0/34 (0/0%)	(1-6)/47 (Range of 2.1-12.8%)
	Total number AE	0	28

Notes: Adverse events related to Weakness, superficial surgical site infection, bleeding at surgical site, serious fluid drainage, triggering, dermatitis, blister/burn, post-surgical nerve entrapment, epidermal maceration, stitches retained in wound, and cellulitis were observed in the Suture group but not in the CoNextions TR group

There were no significant differences in the two study groups related to the frequency of any adverse events. Pain, stiffness, swelling, and neuralgia of the repair sites were the most common adverse events seen in both groups, accounting for 74 of the 126 (58.7%) adverse events affecting the injured digit(s) in the CoNextions TR group. These are known and common adverse events experienced in the postoperative recovery following the surgical repair of lacerated tendons. Adhesion, another known complication following the surgical repair of lacerated tendons is the only other adverse event affecting the injured digit(s) which occurred in more than one participant in the CoNextions TR group (occurring in 2/34 participants, 5.9%).

Serious Adverse Events: All (5) of the serious adverse events (SAE) in the CoNextions TR group affected the injured digit(s). None of these events occurred in more than one participant in the CoNextions TR group. A listing of all serious adverse events related to the injured digit(s) for both study groups is shown in **Table 4**.

Table 4. Serious Adverse Events Affecting the Injured Digit(s)

Serious Adverse Event		CoNextions TR	Suture
Rupture	Participants with AE (Y/N, %)	1/34 (2.9%)	5/47(10.7%)
	Total number AE	1	6
Septic Surgical Site Infection	Participants with AE (Y/N, %)	1/34 (2.9%)	1/47 (2.1%)
	Total number AE	2	1
Device Positioned	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)

Serious Adverse Event		CoNextions TR	Suture
Incorrectly	Total number AE	1	0
Hyperextension injury of injured finger	Participants with AE (Y/N, %)	1/34 (2.9%)	0/47 (0.0%)
	Total number AE	1	0
Superficial Surgical Site Infection	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.1%)
	Total number AE	0	1
Flexion Deformity	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.0%)
	Total number AE	0	1
Post-surgical Nerve Entrapment	Participants with AE (Y/N, %)	0/40 (0.0%)	1/47 (2.1%)
	Total number AE	0	1

There were no significant differences in the two study groups related to the occurrence of these serious adverse events. The rupture in the CoNextions TR group was surgically repaired using a conventional suturing technique (as were the ruptures in the suture group). The CoNextions TR implant was successfully removed as part of the treatment for the septic surgical site infection. In the case of the device being positioned incorrectly in the CoNextions TR group, the implant was removed and replaced with an additional implant at the time of the original surgical repair. The hyperextension injury was a result of additional trauma, considered unrelated to the CoNextions TR device, and treated with additional surgery.

Primary Effectiveness Outcome: The primary effectiveness outcome was the mobility of the repaired digit(s). Strickland's Revised scores were used to provide a descriptive measure of mobility. Strickland Scores are the sum of the active flexion angle of the interphalangeal and metacarpal joints less the extension deficit and are presented as a percentage of a normal value (175). Flexion and extension deficit values were collected using standard finger goniometry methods. Target effectiveness criterion for the study was at least 80% of the CoNextions TR repairs achieving a Strickland Score of 50% or better at the 12 week follow-up visit. This goal was not met; however the primary analysis was supplemented with post-hoc analyses looking at the comparative performance of the two study groups at the final follow-up and the average Strickland mobility scores of the two groups at the 12 and 24 week follow-ups. At the 12 week follow-up, 11 of 27 (40.7%) participants in the CoNextions TR group and 18/41 (43.9%) participants in the Suture group had a Strickland Score of 50% or better. The average Strickland Scores was 47.8 for the CoNextions TR group and 44.0 for the Suture group at the 12 week follow-up. At the 24 week follow-up, 18 of 30 (60.0%) CoNextions TR participants and 24 of 42 (57.1%). Suture participants had a Strickland Score of 50% or better. The average Strickland Scores was 52.7 for the CoNextions TR group and 50.0 for the Suture group at the 12 week follow-up (**Table 5**). No statistically significant differences were seen between the two groups for these safety outcomes

Table 5. Primary Effectiveness Outcome for the Clinical Evaluation

Digital Mobility Outcomes	CoNextions TR	Suture
Strickland Score of At Least 50% at 12 Week Follow-up (Yes/Total, %)	11/27 (40.7%)	18/41 (43.9%)
Average Strickland Mobility Score at 12 Week Follow-Up (95% CI)	47.8% (40.50, 55.10)	44.0% (36.10, 51.90)
Strickland Score of At Least 50% at 24 Week Follow-up (Yes/Total, %)	18/30 (60.0%)	24/42 (57.1%)
Average Strickland Mobility Score at 24 Week Follow-Up (95% CI)	52.7% (44.96, 55.10)	50.0% (41.94, 58.06)

Notes: An error at one site occurred early in the study and resulted in a passive mobility score being recorded for some participants at their 12 week follow-up visit. As a result of this error, there were more participants with active mobility scores at the 24 week follow-up then at the 12 week follow-up.

Secondary Effectiveness Outcomes: VAS Pain Scores, DASH Questionnaire Scores, Grip Strength, and Tip Pinch Strength were assessed as secondary effectiveness outcomes. A 0-10 cm VAS Pain scale was used to assess the patient's self-reported pain. The DASH Questionnaire is a validated metric of functional outcome following intervention in the upper extremity. This questionnaire consists of 30 questions assessing the participants ability to perform various activities of daily living with a score range of 0 (no disability) to 100 (completely disabled). Grip Strengths were collected using a dynamometer and Tip

Pinch Strengths were collected using a pinch gauge. For both strength assessments, the participant was seated with the shoulder adducted and in neutral, the elbow flexed at 90 degrees and the forearm and wrist in neutral position. Both strength assessments are presented as a percentage of the corresponding strength for the contralateral digit (Tip Pinch Strength) or contralateral hand (Grip Strength). There were no statistically significant differences between the two groups for these outcomes at any time point with any differences with any differences between the two groups being less than the reported minimal clinically important difference for the outcome measure (**Table 6**).

Table 6. Secondary Effectiveness Outcomes at Final (24 week) Follow-up

Secondary Effectiveness Outcome	CoNextions TR	Suture
VAS Pain Score at 24 Weeks (N, Average, 95% CI)	N=33 1.2 (0.5, 1.8)	N=42 1.0 (0.5, 1.6)
DASH Questionnaire Scores at 24 Weeks (N, Average, 95% CI)	N=33 12.3 (7.7, 17.0)	N=42 11.5 (6.5, 16.5)
Tip Pinch Strength at 24 Weeks as a % of Contralateral Digit (N, Average, 95% CI)	N=32 73.2% (63.2, 83.3)	N=40 79.4% (72.8, 86.0)
Grip Strength at 24 Weeks as a % of Contralateral Hand (N, Average, 95% CI)	N=33 68.7% (61.8, 75.5)	N=40 73.1% (66.1, 80.2)

Conclusion

The CoNextions TR Tendon Repair System is as safe and effective as the predicate devices. CoNextions TR has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between CoNextions TR and its predicate devices raise no new issues of safety or effectiveness. Performance data, including comparative bench, animal, and clinical testing, demonstrate that the CoNextions TR is as safe and effective as the predicate devices. Thus, CoNextions TR is substantially equivalent.