FDA 510(k) Premarket Notification

K203855 CoNextions TR Tendon Repair System

CLEARED

Apr 22, 2022
477 days to decision

K203855 · Product code: **GAQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile (GAQ)
Date received	Dec 31, 2020
Decision date	Apr 22, 2022
Days to decision	477 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Conextions Medical**
Location	Salt Lake City, UT, US
Contact	Matthew Swift
510(k) history	2 submissions · 2 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03622372

Zone 2 Flexor Tendon Repair With CoNextions TR Implant System

Status	Active not recruiting - *No results published to ClinicalTrials.gov*
Enrollment	90 patients (actual)
Study sites	4 sites
Condition studied	Tendon Injury - Hand
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 1, 2020
Sponsor	CoNextions Medical (Industry)

Primary outcome

Rate of tendon re-rupture

Secondary outcome

Visual Analog Score (VAS) for Pain Assessment (0-10 cm scale)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03622372