FDA 510(k) Premarket Notification

CLEARED

K220833 Citregen Tendon Interference Screw, Citrelock, Citrefix, Citrespline ACL, and Citrelock ACL

Nov 4, 2022
227 days to decision

K220833 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k220833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 22, 2022
Decision date	Nov 4, 2022
Days to decision	227 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acuitive Technologies, Inc.**
Location	Alendale, NJ, US
Contact	Matthew Poggie
510(k) history	6 submissions · 6 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	**BioVera, Inc.**
Contact	Robert A Poggie

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