FDA 510(k) Premarket Notification

K210239 CITRESPLINE and CITRELOCK ACL Implants

CLEARED

Feb 24, 2021
26 days to decision

K210239 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k210239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jan 29, 2021
Decision date	Feb 24, 2021
Days to decision	26 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