FDA 510(k) Premarket Notification

K200725 Citregen Tendon Interference Screw and Citrelock

CLEARED

Oct 7, 2020
202 days to decision

K200725 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k200725/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Mar 19, 2020
Decision date	Oct 7, 2020
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acuitive Technologies**
Location	Alendale, NJ, US
Contact	Jaclyn Docs
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

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

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