FDA 510(k) Premarket Notification

K200301 UNiTi ACDF Implant System

CLEARED

Feb 3, 2021
363 days to decision

K200301 · Product code: **PHQ** · Orthopedic
Source: https://www.510kdatabase.net/k200301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anterior Staple As Supplemental Fixation For Fusion (PHQ)
Date received	Feb 6, 2020
Decision date	Feb 3, 2021
Days to decision	363 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pressio, Inc.**
Location	San Antonio, TX, US
Contact	Joe Ritz
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Empirical Testing Corp**
Contact	Nathan Wright

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