FDA 510(k) Premarket Notification

K200428 Multi-Drive Interference Screw System

CLEARED

Nov 10, 2020
263 days to decision

K200428 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k200428/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Feb 21, 2020
Decision date	Nov 10, 2020
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nvision Biomedical Technologies, Inc.**
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	**Watershed Idea Foundry**
Contact	Jeffrey Brittan

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