FDA 510(k) Premarket Notification

K192417 ARIX Cannulated Screw System

CLEARED

Nov 26, 2019
83 days to decision

K192417 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k192417/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 4, 2019
Decision date	Nov 26, 2019
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jeil Medical Corporation**
Location	Deer Field, IL, US
Contact	Sejin Ryu
510(k) history	53 submissions · 53 cleared · 2002-2026