FDA 510(k) Premarket Notification

K223761 OIC Intramedullary Screw System

CLEARED

Feb 13, 2023
60 days to decision

K223761 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k223761/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 15, 2022
Decision date	Feb 13, 2023
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthopaedic Implant Company**
Location	Reno, NV, US
Contact	Douglas Fulton
510(k) history	10 submissions · 10 cleared · 2014-2024