FDA 510(k) Premarket Notification

K210159 IntraLock System

CLEARED

Jul 23, 2021
183 days to decision

K210159 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k210159/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jan 21, 2021
Decision date	Jul 23, 2021
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fusion Orthopedics, LLC**
Location	Mesa, AZ, US
Contact	Whitney Rey
510(k) history	11 submissions · 11 cleared · 2016-2021