FDA 510(k) Premarket Notification

K230623 KITE Distal Fibula Kit

CLEARED

Sep 1, 2023
179 days to decision

K230623 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k230623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 6, 2023
Decision date	Sep 1, 2023
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intrauma S.P.A**
Location	Rivoli (To), IT
Contact	Piero Costa
510(k) history	3 submissions · 3 cleared · 2021-2025