FDA 510(k) Premarket Notification

K120359 ORTHOLOC 3DI HALLUX SYSTEM

CLEARED

May 3, 2012
87 days to decision

K120359 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k120359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 6, 2012
Decision date	May 3, 2012
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wrightmedicaltechnologyinc**
Location	Arlington, TN, US
Contact	LESLIE FITCH
510(k) history	302 submissions · 291 cleared · 1993-2023