FDA 510(k) Premarket Notification

K131377 HEMICAP MTP RESURFACING HEMI-ARTHROPLASTY IMPLANT

CLEARED

Nov 19, 2013
189 days to decision

K131377 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k131377/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	May 14, 2013
Decision date	Nov 19, 2013
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrosurface, Inc.**
Location	Stoughton, MA, US
Contact	DAWN J WILSON
510(k) history	26 submissions · 26 cleared · 2004-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k131377/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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