FDA 510(k) Premarket Notification

K071243 METAL HEMI IMPLANT

CLEARED

May 23, 2007
20 days to decision

K071243 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k071243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	May 3, 2007
Decision date	May 23, 2007
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Orthopro, LLC**
Location	Round Rock, TX, US
Contact	J.D. WEBB
510(k) history	7 submissions · 7 cleared · 2006-2013