FDA 510(k) Premarket Notification

K031859 CAP GREAT TOE RESURFACING HEMI-ARTHROPLASTY IMPLANT

CLEARED

Feb 18, 2004
247 days to decision

K031859 · Product code: **KWD** · Orthopedic
Source: https://www.510kdatabase.net/k031859/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Jun 16, 2003
Decision date	Feb 18, 2004
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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