FDA 510(k) Premarket Notification

K060127 HEMICAP PATELLO-FEMORAL RESURFACING PROSTHESIS

CLEARED

Mar 16, 2006
57 days to decision

K060127 · Product code: **KRR** · Orthopedic
Source: https://www.510kdatabase.net/k060127/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patello/femoral, Semi-constrained, Cemented, Metal/polymer (KRR)
Date received	Jan 18, 2006
Decision date	Mar 16, 2006
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Arthrosurface, Inc.**
Location	Stoughton, MA, US
Contact	STEVEN W EK
510(k) history	26 submissions · 26 cleared · 2004-2021