FDA 510(k) Premarket Notification

K050966 PIVOT BIPOLAR FEMORAL HEAD

CLEARED

Jul 7, 2005
80 days to decision

K050966 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k050966/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Apr 18, 2005
Decision date	Jul 7, 2005
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ortho Development Corp.**
Location	Draper, UT, US
Contact	WILLIAM J GRIFFIN
510(k) history	45 submissions · 43 cleared · 1996-2025