FDA 510(k) Premarket Notification

K160907 DePuy Actis DuoFix Hip Prosthesis

CLEARED

Jul 19, 2016
109 days to decision

K160907 · Product code: **MEH** · Orthopedic
Source: https://www.510kdatabase.net/k160907/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Uncemented, Metal / Polymer, Non-porous, Calcium Phosphate (MEH)
Date received	Apr 1, 2016
Decision date	Jul 19, 2016
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy(Ireland)**
Location	Cork, IE
Contact	Jaime Weeks
510(k) history	13 submissions · 13 cleared · 2010-2022