FDA 510(k) Premarket Notification

K050138 MODIFICATION TO: RESTORATION MODULAR SYSTEM

CLEARED

Mar 21, 2005
59 days to decision

K050138 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k050138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jan 21, 2005
Decision date	Mar 21, 2005
Days to decision	59 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Howmedica Osteonics Corp.**
Location	Allendale, NJ, US
Contact	KAREN ARIEMMA
510(k) history	288 submissions · 288 cleared · 1999-2020