FDA 510(k) Premarket Notification

K983136 DEPUY LUSTER STEM

CLEARED

Nov 25, 1998
78 days to decision

K983136 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k983136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Sep 8, 1998
Decision date	Nov 25, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DePuy Orthopaedics, Inc.**
Location	Warsaw, IN, US
Contact	SALLY FOUST
510(k) history	206 submissions · 204 cleared · 1998-2023