FDA 510(k) Premarket Notification

K992153 PE-PLUS ACETABULAR CUP

CLEARED

Sep 23, 1999
90 days to decision

K992153 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k992153/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Jun 25, 1999
Decision date	Sep 23, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Plus Orthopedics**
Location	San Diego, CA, US
Contact	HATMUT LOCH
510(k) history	38 submissions · 38 cleared · 1997-2004