FDA 510(k) Premarket Notification

K990330 CROSS LINKED POLYETHYLENE ACETABULAR COMPONENTS,MODEL XX-YY-ZZZZZZ

CLEARED

Mar 1, 2000
393 days to decision

K990330 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k990330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	Feb 2, 1999
Decision date	Mar 1, 2000
Days to decision	393 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Implex Corp.**
Location	Allendale, NJ, US
Contact	ROBERT POGGIE
510(k) history	65 submissions · 61 cleared · 1993-2005