FDA 510(k) Premarket Notification

K971705 IMPLEX HEP ACETABULAR CUP SYSTEM, CEMENTED

CLEARED

Aug 6, 1997
90 days to decision

K971705 · Product code: **JDI** · Orthopedic
Source: https://www.510kdatabase.net/k971705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI)
Date received	May 8, 1997
Decision date	Aug 6, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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