FDA 510(k) Premarket Notification

K892640 PNEUMOTHORAX KIT, MOTIFICATION

CLEARED

Oct 11, 1989
182 days to decision

K892640 · Product code: **JDL** · Orthopedic
Source: https://www.510kdatabase.net/k892640/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained (metal Cemented Acetabular Component) (JDL)
Date received	Apr 12, 1989
Decision date	Oct 11, 1989
Days to decision	182 days
Third-party review	No

APPLICANT

Company	**Arrow Intl., Inc.**
Location	Mchenry, IL, US
Contact	THOMAS D NICKEL
510(k) history	110 submissions · 105 cleared · 1976-2010