FDA 510(k) Premarket Notification

K902365 MODULAR UNIPOLAR SYSTEM

CLEARED

Jan 11, 1991
226 days to decision

K902365 · Product code: **KWL** · Orthopedic
Source: https://www.510kdatabase.net/k902365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal (KWL)
Date received	May 30, 1990
Decision date	Jan 11, 1991
Days to decision	226 days
Third-party review	No

APPLICANT

Company	**Howmedica Corp.**
Location	Mchenry, IL, US
Contact	MARY C SPICER
510(k) history	373 submissions · 325 cleared · 1976-1998