FDA 510(k) Premarket Notification

K023188 PRESS-FIT HEAD RESURFACING DEVICE

CLEARED

Dec 11, 2002
78 days to decision

K023188 · Product code: **KXA** · Orthopedic
Source: https://www.510kdatabase.net/k023188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Femoral, Resurfacing (KXA)
Date received	Sep 24, 2002
Decision date	Dec 11, 2002
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Orthopedics, Inc.**
Location	Warsaw, IN, US
Contact	PATRICIA SANDBORN BERES
510(k) history	34 submissions · 34 cleared · 2000-2008