FDA 510(k) Premarket Notification

K080358 PLLA, HA SCREW

CLEARED

Apr 23, 2008
72 days to decision

K080358 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k080358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 11, 2008
Decision date	Apr 23, 2008
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Smith & Nephew Inc., Endoscopy Div.**
Location	Andover, MA, US
Contact	DEANA BOUSHELL
510(k) history	10 submissions · 10 cleared · 2007-2024