FDA 510(k) Premarket Notification

K041533 SYNTHES (USA) [SYNTHES} PERI-PROSTHETIC SCREWS

CLEARED

Sep 1, 2004
85 days to decision

K041533 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k041533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 8, 2004
Decision date	Sep 1, 2004
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synthes (Usa)**
Location	Mchenry, IL, US
Contact	Lisa Boyle
510(k) history	411 submissions · 394 cleared · 1977-2015