FDA 510(k) Premarket Notification

K083213 SYNTHES 2.7 MM/3.5 MM LCP DISTAL FIBULA PLATES

CLEARED

Dec 30, 2008
60 days to decision

K083213 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k083213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 31, 2008
Decision date	Dec 30, 2008
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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