FDA 510(k) Premarket Notification

K063832 SYNTHES (USA) ELBOW HINGE FIXATOR

CLEARED

Mar 7, 2007
71 days to decision

K063832 · Product code: **LXT** · Orthopedic
Source: https://www.510kdatabase.net/k063832/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component, Metal Composite (LXT)
Date received	Dec 26, 2006
Decision date	Mar 7, 2007
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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