FDA 510(k) Premarket Notification

K033816 SYNTHES (USA) MODIFICATION TO STERNAL RECONSTRUCTION SYSTEM

CLEARED

Mar 2, 2004
84 days to decision

K033816 · Product code: **JDQ** · Orthopedic
Source: https://www.510kdatabase.net/k033816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Dec 9, 2003
Decision date	Mar 2, 2004
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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