FDA 510(k) Premarket Notification

K073281 CAIS STAPLE

CLEARED

May 2, 2008
163 days to decision

K073281 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k073281/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Nov 21, 2007
Decision date	May 2, 2008
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Mitek, A Johnson & Johnson Company**
Location	Norwood, MA, US
Contact	RUTH C FORSTADT
510(k) history	58 submissions · 58 cleared · 2004-2015