FDA 510(k) Premarket Notification

K123668 ORTHOCORD

CLEARED

Feb 26, 2013
89 days to decision

K123668 · Product code: **NEW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Nov 29, 2012
Decision date	Feb 26, 2013
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Mitek, Inc., A Johnson and Johnson Company**
Location	Raynham, MA, US
Contact	TATYANA KORSUNSKY
510(k) history	3 submissions · 3 cleared · 2012-2013