FDA 510(k) Premarket Notification

K103712 GRYPHON PEEK DS ANCHOR W/ ORTHOCORD, GRYPHON PEEK ANCHOR W/ ORTHOCORD

CLEARED

Mar 11, 2011
81 days to decision

K103712 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k103712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 20, 2010
Decision date	Mar 11, 2011
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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