FDA 510(k) Premarket Notification

K082282 HEALIX TI ANCHOR

CLEARED

Nov 7, 2008
88 days to decision

K082282 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k082282/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 11, 2008
Decision date	Nov 7, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Depuy Mitek, A Johnson & Johnson Co.**
Location	Raynham, MA, US
Contact	KRISTINE CHRISTO
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k082282/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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