FDA 510(k) Premarket Notification

K130912 OMNICUT RESECTION BLADE

CLEARED

Jun 14, 2013
73 days to decision

K130912 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k130912/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 2, 2013
Decision date	Jun 14, 2013
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k130912/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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