FDA 510(k) Premarket Notification

K130169 FMS VUE FLUID MANAGMENT SYSTEM, FMS CONNECT INTERFACE CABLE

CLEARED

May 1, 2013
97 days to decision

K130169 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k130169/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jan 24, 2013
Decision date	May 1, 2013
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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