

K151125 AVAflex Vertebral Balloon SystemNov 24, 2015
210 days to decisionK151125 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k151125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 28, 2015
Decision date	Nov 24, 2015
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Care Fusion
Location	Waukegan, IL, US
Contact	Joy Greidanus
510(k) history	34 submissions · 29 cleared · 2010-2024

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