FDA 510(k) Premarket Notification

K131824 AVAFLEX VERTEBRAL BALLOON SYSTEM

CLEARED

Oct 3, 2013
105 days to decision

K131824 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k131824/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jun 20, 2013
Decision date	Oct 3, 2013
Days to decision	105 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