FDA 510(k) Premarket Notification

K103064 AVAMAX VERTEBRAL BALLOON

CLEARED

Jan 10, 2011
84 days to decision

K103064 · Product code: **NDN** · Orthopedic
Source: https://www.510kdatabase.net/k103064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Oct 18, 2010
Decision date	Jan 10, 2011
Days to decision	84 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