FDA 510(k) Premarket Notification

K043048 GRAFTON PLUS DBM PASTE

CLEARED

Nov 23, 2005
384 days to decision

K043048 · Product code: **MBP** · Orthopedic
Source: https://www.510kdatabase.net/k043048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Osteoinduction (w/o Human Growth Factor) (MBP)
Date received	Nov 4, 2004
Decision date	Nov 23, 2005
Days to decision	384 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteotech, Inc.**
Location	San Mateo, CA, US
Contact	CHRISTOPHER TALBOT
510(k) history	24 submissions · 21 cleared · 1985-2008