FDA 510(k) Premarket Notification

K060180 BIOSET XC

CLEARED

Sep 6, 2006
226 days to decision

K060180 · Product code: **MBP** · Orthopedic
Source: https://www.510kdatabase.net/k060180/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Osteoinduction (w/o Human Growth Factor) (MBP)
Date received	Jan 23, 2006
Decision date	Sep 6, 2006
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Regeneration Technologies, Inc.**
Location	Alachua, FL, US
Contact	Lisa Simpson
510(k) history	11 submissions · 11 cleared · 2005-2008