FDA 510(k) Premarket Notification

K090855 EQUIVABONE OSTEOINDUCTIVE BONE GRAFT SUBSTITUTE

CLEARED

Sep 18, 2009
172 days to decision

K090855 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k090855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Mar 30, 2009
Decision date	Sep 18, 2009
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Etex Corp.**
Location	Cambridge, MA, US
Contact	CHRISTOPHER KLACZYK
510(k) history	18 submissions · 17 cleared · 1994-2010