

K082575 ACTIFUSE BONE GRAFT SUBSTITUTE AND ABX E-Z-FIL AND SHAPE BONE GRAFT SUBSTITUTESNov 25, 2008
81 days to decisionK082575 · Product code: **MQV** · Orthopedic
Source: <https://www.510kdatabase.net/k082575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Sep 5, 2008
Decision date	Nov 25, 2008
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Apatech , Ltd.
Location	Waltham, MA, US
Contact	CANDACE F CEDERMAN
510(k) history	8 submissions · 8 cleared · 2004-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082575/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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