

K081817 ACCELL TBM-RSep 24, 2008
90 days to decisionK081817 · Product code: **MBP** · Orthopedic
Source: <https://www.510kdatabase.net/k081817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Osteoinduction (w/o Human Growth Factor) (MBP)
Date received	Jun 26, 2008
Decision date	Sep 24, 2008
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isotis Orthobiologics, Inc.
Location	Bilthoven, NL
Contact	JUDITH E O'GRADY
510(k) history	10 submissions · 10 cleared · 2004-2009

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