

K041382 POLYGRAFT BGSJun 17, 2005
388 days to decisionK041382 · Product code: **JDK** · Orthopedic
Source: <https://www.510kdatabase.net/k041382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	May 25, 2004
Decision date	Jun 17, 2005
Days to decision	388 days
Third-party review	No
Summary / Statement	Summary
Other names	BONE GRAFT SUBSTITUTE

APPLICANT

Company	Osteobiologics, Inc.
Location	San Antonio, TX, US
Contact	GABRIELE G NIEDERAUER, PH.D.
510(k) history	9 submissions · 8 cleared · 2002-2005

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