

K063857 SIMPLEX P SPEEDSET WITH TOBRAMYCIN BONE CEMENTFeb 26, 2007
60 days to decisionK063857 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k063857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Dec 28, 2006
Decision date	Feb 26, 2007
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Howmedica Osteonics Corp.
Location	Allendale, NJ, US
Contact	TIFFANI ROGERS
510(k) history	288 submissions · 288 cleared · 1999-2020

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