

**K081163 SMARTSET GMV GENTAMICIN BONE CEMENT**May 14, 2008  
20 days to decisionK081163 · Product code: **MBB** · Orthopedic  
Source: <https://www.510kdatabase.net/k081163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Apr 24, 2008
Decision date	May 14, 2008
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DePuy Orthopaedics, Inc.</b>
Location	Warsaw, IN, US
Contact	SUZANA OTANO
510(k) history	206 submissions · 204 cleared · 1998-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081163/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026