

**K111593 GUARDIAN INFLATABLE BONE EXPANDER SYSTEM**Nov 18, 2011  
164 days to decisionK111593 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k111593/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Jun 7, 2011
Decision date	Nov 18, 2011
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bm Korea Co., Ltd.</b>
Location	Marietta, GA, US
Contact	RONALD D ARKIN
510(k) history	5 submissions · 5 cleared · 2011-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111593/> 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 17, 2026