

**K112907 CONFIDENCE HIGH VISCOSITY SPINAL CEMENT, 16G  
/ 20G**Dec 22, 2011  
80 days to decisionK112907 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k112907/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Oct 3, 2011
Decision date	Dec 22, 2011
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medos International SARL</b>
Location	Raynham, MA, US
Contact	ROBIN DINARDO
510(k) history	96 submissions · 96 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112907/>; 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 18, 2026