

**K110998 AFFIRM (TM) VCF SYSTEM**Oct 25, 2011  
197 days to decisionK110998 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k110998/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Apr 11, 2011
Decision date	Oct 25, 2011
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Algea Therapies</b>
Location	Audubon, PA, US
Contact	KELLY J BAKER
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110998/> 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