

**K112399 UNITE BIOMATRIX**Sep 7, 2011  
19 days to decisionK112399 · Product code: **KGN** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k112399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wound Dressing With Animal-derived Material(s) (KGN)
Date received	Aug 19, 2011
Decision date	Sep 7, 2011
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synovis Orthopedic &amp; Woundcare</b>
Location	Irvine, CA, US
Contact	AMY BOUCLY
510(k) history	3 submissions · 3 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112399/> 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