

**K112786 PROSERIES BIOIMPLANTS-PROANKLE/PROCUFF**Oct 25, 2011  
29 days to decisionK112786 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k112786/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Sep 26, 2011
Decision date	Oct 25, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synovis Orthopedic and Woundcare, Inc.</b>
Location	Irvine, CA, US
Contact	AMY BOUCLY
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/k112786/> 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 June 18, 2026