

**K083307 SYNTHASOME X-REPAIR**Mar 27, 2009  
137 days to decisionK083307 · Product code: **FTL** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k083307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 10, 2008
Decision date	Mar 27, 2009
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthasome, Inc.</b>
Location	San Diego, CA, US
Contact	ANTHONY RATCLIFFE
510(k) history	2 submissions · 2 cleared · 2009-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083307/> 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 6, 2026