

**K130324 STATSEAL DISC**Jul 9, 2013  
151 days to decisionK130324 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k130324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Feb 8, 2013
Decision date	Jul 9, 2013
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolife, LLC</b>
Location	Sarasota, FL, US
Contact	CLAUDIA MASSELINK
510(k) history	3 submissions · 3 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130324/> 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 8, 2026