

**K101097 CALGAESEAL MODEL: CAS**Sep 22, 2010  
155 days to decisionK101097 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k101097/>**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	Apr 20, 2010
Decision date	Sep 22, 2010
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bz Medical, Inc.</b>
Location	Portland, OR, US
Contact	BYRON ZAHLER
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101097/> 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 20, 2026