

**K112864 SOFTSEAL-C**Aug 2, 2012  
307 days to decisionK112864 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k112864/>**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	Sep 30, 2011
Decision date	Aug 2, 2012
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chitogen, Inc.</b>
Location	Minneapolis, MN, US
Contact	JAMES F DRAKE
510(k) history	2 submissions · 2 cleared · 2009-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112864/> 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 14, 2026