

**K151204 HEMO-Bandage**Jul 31, 2015  
87 days to decisionK151204 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k151204/>**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	May 5, 2015
Decision date	Jul 31, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coreleader Biotech Co., Ltd.</b>
Location	Taipei, Taiwan, TW
Contact	Ya-Wen Kuo
510(k) history	9 submissions · 9 cleared · 2011-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151204/> 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 4, 2026