

**K121485 GUARDIVA ANTIMICROBIAL HAEMSTATIC IV DRESSING**Aug 21, 2012  
95 days to decisionK121485 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k121485/>**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 18, 2012
Decision date	Aug 21, 2012
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemcon Medical Technologies Europe, Ltd.</b>
Location	Portland, OR, US
Contact	BARBARA MCGRATH
510(k) history	3 submissions · 3 cleared · 2010-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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