

**K130350 PROCELLERA**Jul 2, 2013  
140 days to decisionK130350 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k130350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 12, 2013
Decision date	Jul 2, 2013
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vomaris Innovations, Inc.</b>
Location	Chandler, AZ, US
Contact	Mary Maijer
510(k) history	2 submissions · 2 cleared · 2013-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130350/> 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 2, 2026