

**K163645 DERMABOND PRINEO Skin Closure System**Apr 21, 2017  
119 days to decisionK163645 · Product code: **OMD** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Tissue Adhesive With Mesh (OMD)
Date received	Dec 23, 2016
Decision date	Apr 21, 2017
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ethicon, LLC</b>
Location	Los Frailes Industrial Park, Suite 401, PR, US
Contact	Joice Pappan
Website	<a href="http://www.ethiconinc.com">http://www.ethiconinc.com</a>
510(k) history	2 submissions · 2 cleared · 2016-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163645/>; 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 1, 2026