

**K151237 Nutrisafe 2- ENFit Adaptor**Feb 9, 2016  
274 days to decisionK151237 · Product code: **PIO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k151237/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteral Specific Transition Connectors (PIO)
Date received	May 11, 2015
Decision date	Feb 9, 2016
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vygon</b>
Location	Lansdale Montgomery, PA, US
Contact	Jillian Mikovich
510(k) history	2 submissions · 2 cleared · 2014-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151237/> 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 3, 2026