

**K132464 PTFE SURGICAL SUTURE**Feb 12, 2014  
189 days to decisionK132464 · Product code: **NBY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k132464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene (NBY)
Date received	Aug 7, 2013
Decision date	Feb 12, 2014
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Omnia Spa</b>
Location	Carmel, IN, US
Contact	MARCO MANDUCHI
510(k) history	3 submissions · 3 cleared · 2011-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132464/> 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 May 30, 2026