

**K100780 VITAL SUTURES, SUTUREX, CIRUGIA PERUANA**Dec 14, 2010  
270 days to decisionK100780 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100780/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Mar 19, 2010
Decision date	Dec 14, 2010
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unilene Sac</b>
Location	Greenwood Village, CO, US
Contact	KEVIN WALLS, RAC
510(k) history	2 submissions · 2 cleared · 2010-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100780/> 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 9, 2026