

**K063136 NEEDLELESS SLING**Dec 19, 2006  
64 days to decisionK063136 · Product code: **PAH** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k063136/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH)
Date received	Oct 16, 2006
Decision date	Dec 19, 2006
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Specialities Remeex International, S.L.</b>
Location	Minneapolis, MN, US
Contact	JEFFREY R SHIDEMAN
510(k) history	3 submissions · 3 cleared · 2004-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063136/> 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 29, 2026