

K110420 OPHIRA MINI SLING SYSTEMMay 8, 2012
449 days to decisionK110420 · Product code: **PAH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k110420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH)
Date received	Feb 14, 2011
Decision date	May 8, 2012
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Promedon S.A
Location	Piscataway, NJ, US
Contact	STEPHANIE RAIS
510(k) history	1 submissions · 1 cleared · 2012-2012

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