

K121641 MINIARC PRO SINGLE-INCISION SLING SYSTEMSep 7, 2012
95 days to decisionK121641 · Product code: **PAH** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k121641/>**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	Jun 4, 2012
Decision date	Sep 7, 2012
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems
Location	Minnetonka, MN, US
Contact	RENEE MELLUM
Website	http://www.varian.com
510(k) history	10 submissions · 10 cleared · 2008-2014

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