

**K100807 MINIARC PRECISE SINGLE-INCISION SLING SYSTEM
MODEL: 720181, 720191**Jun 7, 2010
77 days to decisionK100807 · Product code: **PAH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100807/>**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	Mar 22, 2010
Decision date	Jun 7, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Medical Systems, Inc.
Location	Mchenry, IL, US
Contact	DONNA SEMLAK
510(k) history	72 submissions · 72 cleared · 1979-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100807/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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