

K090934 PFR SLING SYSTEM, PART OF THE AMS PELVIC FLOOR REPAIR SYSTEMJun 2, 2009
61 days to decision

K090934 · Product code: FTL · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k090934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 2, 2009
Decision date	Jun 2, 2009
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090934/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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