

K081613 SPARC SYSTEM / MONARC, MONARC C, MONARC + SYSTEMSSep 17, 2008
100 days to decisionK081613 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k081613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jun 9, 2008
Decision date	Sep 17, 2008
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081613/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026