

K041948 SPARC, MONARC, BIOARC SP AND BIOARC TO SLING SYSTEMSAug 11, 2004
22 days to decisionK041948 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k041948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jul 20, 2004
Decision date	Aug 11, 2004
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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