

K132655 RETROARC RETROPUBIC SLING SYSTEMNov 20, 2013
86 days to decisionK132655 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k132655/>**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	Aug 26, 2013
Decision date	Nov 20, 2013
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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