

**K131229 SPARC SYSTEM AND MONARC, MONARC, AND MONARC C SYSTEMS**Dec 5, 2013  
219 days to decisionK131229 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k131229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Apr 30, 2013
Decision date	Dec 5, 2013
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medical Systems</b>
Location	Minnetonka, MN, US
Contact	TODD HILDEBRANDT
Website	<a href="http://www.varian.com">http://www.varian.com</a>
510(k) history	10 submissions · 10 cleared · 2008-2014

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