

**K210087 Athena Surgical RMUS System**Apr 12, 2021  
89 days to decisionK210087 · Product code: **OTN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k210087/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Jan 13, 2021
Decision date	Apr 12, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Athena Surgical, LLC</b>
Location	Minnetonka, MN, US
Contact	Greg Slusser
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medavise Consulting</b>
Contact	Kellen Hills

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210087/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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