

**K231891 Virtue Male Sling System with Alexis Wound Retractor Convenience Kit**Sep 25, 2023  
90 days to decisionK231891 · Product code: **OTM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k231891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Mesh, Surgical, For Stress Urinary Incontinence, Male (OTM)
Date received	Jun 27, 2023
Decision date	Sep 25, 2023
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coloplast</b>
Location	Plymouth, MN, US
Contact	Jennifer Mrkvicka
Website	<a href="http://www.coloplast.com/">http://www.coloplast.com/</a>
510(k) history	15 submissions · 14 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231891/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026