

**K240037 Revi™ System**May 2, 2024  
118 days to decisionK240037 · Product code: **QXM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implanted Tibial Electrical Urinary Continence Device (QXM)
Date received	Jan 5, 2024
Decision date	May 2, 2024
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bluewind Medical , Ltd.</b>
Location	Herzliya, IL
Contact	Jason Woehrle
510(k) history	3 submissions · 2 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240037/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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