

K252391 Revi SystemDec 12, 2025
134 days to decisionK252391 · Product code: **QXM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implanted Tibial Electrical Urinary Continence Device (QXM)
Date received	Jul 31, 2025
Decision date	Dec 12, 2025
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bluewind Medical , Ltd.
Location	Herzliya, IL
Contact	Angel Estrada
510(k) history	3 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	BioVision , Ltd.
Contact	Elissa Burg

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252391/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026