FDA 510(k) Premarket Notification

K253651 Revi System

CLEARED

Jul 28, 2026
250 days to decision

K253651 · Product code: **QXM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k253651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implanted Tibial Electrical Urinary Continence Device (QXM)
Date received	Nov 20, 2025
Decision date	Jul 28, 2026
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bluewind Medical , Ltd.**
Location	Herzliya, IL
Contact	Angel Estrada
510(k) history	4 submissions · 3 cleared · 2023-2026