FDA 510(k) Premarket Notification

K240037 Revi™ System

CLEARED

May 2, 2024
118 days to decision

K240037 · Product code: **QXM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240037/

SUBMISSION DETAILS

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

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