FDA 510(k) Premarket Notification

K223595 vPATCH

CLEARED

May 1, 2023
150 days to decision

K223595 · Product code: **QRC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k223595/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-implanted Electrical Stimulation Device For Management Of Premature Ejaculation (QRC)
Date received	Dec 2, 2022
Decision date	May 1, 2023
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Virility Medical , Ltd.**
Location	Hod-Hasharon, IL
Contact	Tal Golan
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**ProMedoss, Inc.**
Contact	Bosmat Friedman

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