

K252809 in2 Smart (in2S)Apr 6, 2026
215 days to decisionK252809 · Product code: **QRC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-implanted Electrical Stimulation Device For Management Of Premature Ejaculation (QRC)
Date received	Sep 3, 2025
Decision date	Apr 6, 2026
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252809/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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