

K253285 Elitone for Men

Jan 23, 2026
116 days to decision

K253285 · Product code: **QAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253285/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Electrode Stimulator For Urinary Incontinence (QAJ)
Date received	Sep 29, 2025
Decision date	Jan 23, 2026
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elidah, Inc.
Location	Monroe, CT, US
Contact	Gloria Kolb
510(k) history	3 submissions · 3 cleared · 2019-2026

CLINICAL EVIDENCE - NCT06620419

Clinical Study of External Electrical Stimulation for Male Incontinence

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	30 patients (estimated)
Study sites	1 site
Condition studied	Urinary Incontinence
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jun 30, 2026
Sponsor	Elidah, Inc. (Industry)

Primary outcome

Reduction in Leakage by Pad weight

Secondary outcome

Safety measured by no Adverse events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06620419
