

K223884 ELITONE Urge Urinary Incontinence DeviceFeb 24, 2023
59 days to decisionK223884 · Product code: **QAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k223884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Electrode Stimulator For Urinary Incontinence (QAJ)
Date received	Dec 27, 2022
Decision date	Feb 24, 2023
Days to decision	59 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 - NCT04752709**Efficacy of Surface Electrical Stimulation for Urge Urinary Incontinence in Women**

Status	Completed
Enrollment	82 patients (actual)
Study sites	1 site
Condition studied	Urge Incontinence
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Quadruple
Completion date	Sep 30, 2021
Sponsor	Elidah, Inc. (Industry)

Primary outcome

Change in Average Number of Urinary Incontinence Episodes Per Day

Secondary outcome

Efficacy Assessed by Change in Incontinence Quality of Life Questionnaire (I-QOL)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04752709