

K183585 Elitone DeviceFeb 11, 2019
52 days to decisionK183585 · Product code: **QAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Electrode Stimulator For Urinary Incontinence (QAJ)
Date received	Dec 21, 2018
Decision date	Feb 11, 2019
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183585/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026