FDA 510(k) Premarket Notification

K183585 Elitone Device

CLEARED

Feb 11, 2019
52 days to decision

K183585 · 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