FDA 510(k) Premarket Notification

K230526 TEA Device

CLEARED

Sep 14, 2023
199 days to decision

K230526 · Product code: **QHH** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230526/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-implanted Nerve Stimulator For Pain Associated With Irritable Bowel Syndrome (ibs) (QHH)
Date received	Feb 27, 2023
Decision date	Sep 14, 2023
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Transtimulation Research, Inc.**
Location	Oklahoma City, OK, US
Contact	Jieyun Yin
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**AlvaMed, Inc.**
Contact	Eric Bannon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT05392439

Effect of taVNS on Abdominal Pain and Other Symptoms in Constipation-predominant Irritable Bowel Syndrome

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	42 patients (actual)
Study sites	1 site
Condition studied	Constipation-predominant Irritable Bowel Syndrome; Abdominal Pain
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	Dec 15, 2020
Sponsor	Tongji University (Other)

Primary outcome

Change in ?bdominal pain between sham and active taVNS

Secondary outcome

Change in IBS symptom severity scale (IBS-SSS) between sham and active taVNS

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05392439