

# K220454 Vivally System Wearable, Non-Invasive Neuromodulation System and Mobile Application

Apr 3, 2023  
410 days to decision

K220454 · Product code: **NAM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k220454/>

## SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Peripheral Nerve, Non-implanted, For Urinary Incontinence (NAM)
Date received	Feb 17, 2022
Decision date	Apr 3, 2023
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

Company	<b>Avation Medical, Inc.</b>
Location	Columbus, OH, US
Contact	Manish Vaishya
510(k) history	1 submissions · 1 cleared · 2023-2023

## CLINICAL EVIDENCE - NCT04547920

### FREEOAB Study for Overactive Bladder

Status	Completed
Enrollment	96 patients (actual)
Study sites	9 sites
Condition studied	Overactive Bladder; Urinary Frequency; Urinary Incontinence, Urge; Urinary Urgency
Primary purpose	Treatment
Study type	Interventional
Study design	Sequential
Masking	Open label
Completion date	Jun 15, 2023
Sponsor	Avation Medical, Inc. (Industry)

#### Primary outcome

Percentage of Responders in Voiding (Urinary Frequency) Events

#### Secondary outcome

Percentage of Responders in Incontinence (Leak) Events (IE)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04547920](https://clinicaltrials.gov/study/NCT04547920)