FDA 510(k) Premarket Notification

K252339 iotaSOFT® Insertion System

CLEARED

Jan 9, 2026
165 days to decision

K252339 · Product code: **QQH** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k252339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Insertion System For A Cochlear Implant Electrode Array (QQH)
Date received	Jul 28, 2025
Decision date	Jan 9, 2026
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Iotamotion, Inc.**
Location	Iowa City, IA, US
Contact	Khamporn Pendergrass
510(k) history	2 submissions · 1 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Darthur Consulting**
Contact	Deborah Arthur

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

CLINICAL EVIDENCE - NCT06106373

iotaSOFT Pediatric Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	20 patients (actual)
Study sites	2 sites
Condition studied	Hearing Loss, Sensorineural; Hearing Loss, Bilateral; Hearing Loss, Unilateral
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 10, 2025
Sponsor	iotaMotion, Inc. (Industry)

Primary outcome

Safety related to adverse events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06106373

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252339/ Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026