

K242672 Zoom System

Jan 14, 2025
130 days to decision

K242672 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k242672/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Sep 6, 2024
Decision date	Jan 14, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imperative Care, Inc.
Location	Sunnyvale, CA, US
Contact	Teri Nguyen
510(k) history	17 submissions · 17 cleared · 2018-2025

CLINICAL EVIDENCE - NCT04129125

The Imperative Trial: Treatment of Acute Ischemic Stroke With the Zoom Reperfusion System

Status	Completed
Enrollment	328 patients (actual)
Study sites	28 sites
Condition studied	Ischemic Stroke; Acute Stroke
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 28, 2024
Sponsor	Imperative Care, Inc. (Industry)

Primary outcome

ITT Cohort: Rate of Core Lab-adjudicated Reperfusion Success

Secondary outcome

ITT Cohort: Time to Achieve mTICI Score ? 2b

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04129125