

K222694 EmPro EPS (EP4514C-190, EP6514C-190)Apr 27, 2023
233 days to decisionK222694 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k222694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Sep 6, 2022
Decision date	Apr 27, 2023
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Nanoparasol EPS (PNP4514C-190, PNP6514C-190)

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	Ganesh Balachandar
510(k) history	85 submissions · 85 cleared · 2001-2024

CLINICAL EVIDENCE - NCT02657707**Evaluation of the Roadsaver Stent Used in Conjunction With the Nanoparasol Embolic Protection System for Carotid Artery Stenosis**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	295 patients (estimated)
Study sites	37 sites
Condition studied	Carotid Artery Stenosis
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 1, 2024
Sponsor	Microvention-Terumo, Inc. (Industry)

Primary outcome

All stroke, death, and MI

Secondary outcome

Successful deployment of stent

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02657707