SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name:	Stent, Carotid
Device Trade Name:	CGuard® Prime TransCarotid Stent System
Device Procode:	NIM
Applicant's Name and Address:	InspireMD, Ltd. Menorat Hamaor 4 Tel Aviv, Israel 67448
Date(s) of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P240029/S005
Date of FDA Notice of Approval:	November 9, 2026

The original PMA (P240029) for the CGuard Prime Carotid Stent System in the 135 cm delivery system length was approved on June 23, 2025.

CGuard Prime Carotid Stent System, when used in conjunction with embolic protection devices specified in the labeling, is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet both criteria outlined below:

- Patients with neurological symptoms and ≥50% stenosis of the common or internal carotid artery by angiogram or patients without neurological symptoms and ≥80% stenosis of the common or internal carotid artery by angiogram.

- Patients having a vessel with reference diameters between 6.4 mm and 9.0 mm at the target lesion.

This supplement was submitted to obtain approval for the CGuard Prime TransCarotid Stent System with a shorter delivery system (80 cm instead of 135 cm) to facilitate stent implantation using the transcarotid artery revascularization (TCAR) approach. Aside from this modification, the delivery system and stent are identical to those approved in the original PMA.

The SSED to support the indication for the CGuard Prime Carotid Stent System - 135cm version is available on the CDRH website and incorporated into the current SSED by reference here.

II. INDICATIONS FOR USE

The CGuard Prime TransCarotid Stent System, when used in conjunction with an embolic protection system specified in the labeling, is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined below:

- Patients with neurological symptoms and ≥ 50% stenosis of the common or internal carotid artery by angiogram, or patients without neurological symptoms and ≥ 80% stenosis of the common or internal carotid artery by angiogram.
- Patients having a vessel with reference diameters between 6.4mm and 9.0mm at the target lesion.
- A carotid bifurcation location that is at least 5 cm above the clavicle, verified through duplex Doppler ultrasound, CT angiography, or MR angiography.

III. CONTRAINDICATIONS

The CGuard Prime TransCarotid Stent System is contraindicated for use in:

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated
- Patients with whom a transcarotid neuroprotection system cannot be effectively placed
- Patients with known hypersensitivity to nickel-titanium
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the CGuard Prime TransCarotid Stent System labeling.

V. DEVICE DESCRIPTION

The InspireMD CGuard Prime TransCarotid Stent System is designed to deliver a self-expanding stent to the carotid arteries using a rapid exchange (Rx) delivery system. The CGuard Prime TransCarotid Stent System that is the subject of this PMA supplement is designed with a shorter delivery system length (80 cm versus 135 cm) to facilitate stent implantation via the transcarotid artery revascularization (TCAR) approach. Besides this change, the delivery system and stent are identical to those approved in the original PMA.

The self-expanding stent is constructed of a nickel-titanium alloy (Nitinol) and is covered by a permanent protective micromesh (MicroNet™). The stent is loaded into the Rx delivery system. The delivery system is placed at the intended lesion site, and then the stent is expanded by retraction of a protective sheath. The stent and micromesh remain as a permanent vessel scaffolding implant. Upon deployment, the stent imparts an outward radial force on the arterial wall to establish lumen patency. The stent is intended for straight vessels and is available in the size matrix shown in **Table 1.**

Table 1: CGuard Prime Carotid Stent Size Matrix

Reference Vessel Diameter (mm)	Length (mm)		
	Diameter (mm)	30	40
6.4 – 7.3	8.0	CNS0830	CNS0840
7.2 – 8.1	9.0	CNS0930	CNS0940
8.0 – 9.0	10.0	CNS1030	CNS1040

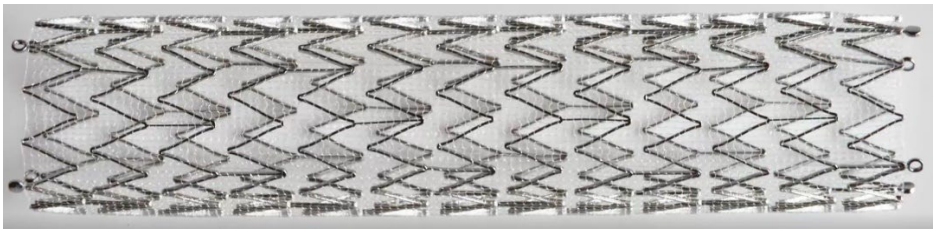


Figure 1: CGuard Prime Carotid Stent

The CGuard Prime TransCarotid Stent System deploys using a two-step process: a pre-release (step 1), and stent deployment (step 2), which is the same as the CGuard Prime Carotid Stent System 135cm version. The delivery system is the same for all sizes of the CGuard Prime Carotid Stent. It is comprised of an outer shaft and an inner assembly. A pictorial representation of the delivery system is presented in **Figure 2**.

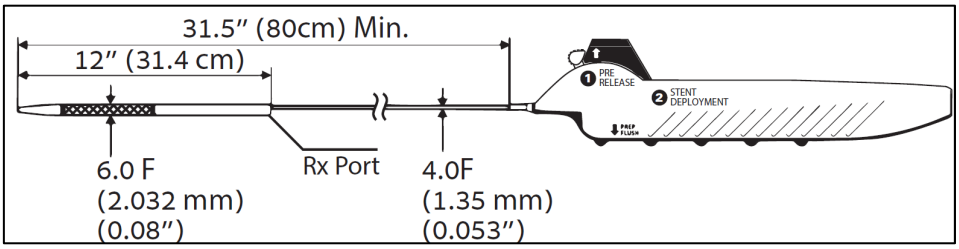


Figure 2: Rx Delivery System of 80cm working length

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternative practices and procedures for the treatment of carotid artery disease which are dependent on symptomatic status, patient anatomy and comorbidities, and degree of stenosis. Patients with less severe disease or symptoms are generally treated with lifestyle modifications and medical management including antiplatelet and/or anticoagulant medicine, antihypertensive or antilipidemic drugs. Carotid endarterectomy and carotid artery stenting are alternative treatments, particularly with more severe disease. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The CGuard Prime TransCarotid Stent System has not been marketed in any country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

For the specific adverse events that occurred in the clinical study, please see Section X.D below.

- Abrupt vessel closure
- Allergic reaction (contrast medium; drug; stent or filter material)
- Amaurosis fugax
- Aneurysm or pseudoaneurysm in the vessel or at the vascular access site
- Angina/coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial and/or ventricular tachycardia, atrial and/or ventricular fibrillation)
- Asystole or bradycardia
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication
- Cardiac tamponade
- Cardiogenic shock
- Carotid artery spasm
- Cerebral edema
- Cerebral hemorrhage
- Cerebral ischemia
- Congestive heart failure (CHF)
- Death
- Detachment and/or implantation of a component of the system
- Dissection of blood vessel
- Emboli (air, tissue, plaque, thrombotic material, stent)
- Emergency artery bypass graft surgery
- Emergent or urgent carotid endarterectomy
- Emergent surgery to remove stent.
- Hematoma at the vascular access site, with or without surgical repair
- Hemorrhagic event, with or without transfusion
- Hyperperfusion syndrome
- Hypotension/hypertension
- Infection, local or systemic, including bacteremia or septicemia
- Ischemia/ infarction of tissue organ
- Myocardial infarction
- New or worse encephalopathy
- Pain
- Pain at the catheter insertion site

- Pericardial effusion
- Pulmonary edema
- Renal failure/insufficiency
- Respiratory failure
- Restenosis of the stented segment
- Seizure
- Severe unilateral headache
- Stent collapse or fracture
- Stent malposition/migration
- Stent thrombosis or occlusion
- Stroke / Cerebrovascular accident (CVA)
- Transient ischemic attack (TIA)
- Tissue necrosis
- Total occlusion of the carotid artery
- Vascular thrombosis/occlusion at the access site, treatment site, or remote site
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil

IX. SUMMARY OF NON-CLINICAL STUDIES

Because the CGuard Prime TransCarotid Stent System is identical to the CGuard Prime Carotid Stent System 135cm version with the exception of the delivery system length, a majority of the non-clinical testing was leveraged from the original PMA P240029. This included biocompatibility, stent engineering testing and material properties, packaging integrity for the claimed shelf-life, sterilization validation and animal studies relevant to the CGuard Prime TransCarotid Stent System with its shorter 80cm delivery catheter. Please see the P240029 SSED for details of the non-clinical testing that was conducted to obtain approval for the CGuard Prime Carotid Stent System 135cm version.

In addition, testing was performed to assess the delivery system and functional attributes relevant to stent implantation using the TCAR approach and the CGuard Prime TransCarotid Stent System with the commercially available ENROUTE™ Transcarotid Neuroprotection System as described below.

A. Engineering Testing

In vitro bench testing to support the CGuard Prime TransCarotid Stent System was developed based on the device risk assessment and is consistent with the following FDA guidance documents:

- "Non-Clinical Tests and Recommended Labeling of Intravascular Stents and Associated Delivery Systems", April 18, 2010, and its addendum.
- "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems", August 18, 2015.

The relevant bench tests outlined in the guidance document and included in support of the CGuard Prime TransCarotid Stent System are summarized in **Table 2** below.

Table 2: CGuard Prime TransCarotid Stent System Bench Testing

Test	Purpose	Acceptance Criteria	Results
Delivery System Dimensional and Functional Attributes			
Dimensional Verification	To verify the usable length of the delivery system meets specification	The delivery system usable length is 800 +10mm	PASS
Flushing	To verify the delivery system is able to inject saline and flush the main lumen and the stent outer sheath	When flushed per the IFU with at least 2 cc of saline using a 3 cc or 5 cc syringe, saline must not exit from any location other than the distal tip and RX port.	PASS
Trackability	To verify the delivery system is capable of reaching the target lesion site over a guidewire without excessive resistance, loss of control, or damage to the delivery system.	The delivery system must reach the target site through the anatomical path without displacement of the guidewire or damage to the delivery system.	PASS
Pushability	To verify the delivery system is capable of reaching the target lesion site over a guidewire without excessive resistance, loss of control, or damage to the delivery system.	Push force ≤ 10 N in both Enroute flow controller positions (High and Low).	PASS
Torque Resistance – Before Stent Deployment	The verify the delivery system is able to withstand torquing and maintain structural integrity before and after stent deployment	The system shall withstand one (1) complete turn (360 degrees) clockwise, then return to the initial position of the system and withstand one (1) complete turn counterclockwise, without a kink in the body of the delivery system or failure of a bond.	PASS
Deployment Force	To verify the delivery system enables controlled stent deployment by minimizing friction between internal components, while maintaining lumen integrity and trackability.	Deployment force ≤ 15 N in both Enroute flow controller positions (High and Low).	PASS

Test	Purpose	Acceptance Criteria	Results
Deployment Accuracy	To verify the delivery system can place the stent at the intended target location without unintended stent movement	± 2.5 mm from the target location in both Enroute flow controller positions (High and Low).	PASS
Torque Resistance	To verify the delivery system is able to withstand torquing and maintain structural integrity before and after stent deployment	The system shall withstand five (5) complete turns (360 degrees, clockwise or counterclockwise) and then return to the initial position of the system without a kink in the body of the delivery system or failure of a bond.	PASS
Retraction Force	To verify the delivery system can be withdrawn from the target lesion site after stent deployment without excessive resistance	Retraction force ≤ 10 N in both Enroute flow controller positions (High and Low).	PASS
Kink Resistance	To verify the delivery system shaft can maintain structural integrity and guidewire lumen patency throughout its working length.	All delivery catheters shall resist kinking when used in a challenging curve condition in the internal carotid artery (ICA). In visual inspection, no kink or catheter damage shall be observed after simulated use in the TCAR model	PASS
Stent Integrity	To verify the stent integrity is maintained throughout entire use of device (loading, delivery, and deployment)	All stents used in the simulated use testing shall be visually inspected along the entire length and circumference for stent integrity. All stents must be free of the following: – Fractures in the nitinol stent – Damage to the inner lumen side – Sleeve protrusion into the vessel lumen – Damage to the sleeve component or loose ends	PASS

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study (CGUARDIANS II) to establish a reasonable assurance of safety and effectiveness of carotid artery stenting with the CGuard Prime TransCarotid Stent System in patients at high risk for adverse events from carotid endarterectomy (CEA) in the United States (US) under Investigational Device Exemption (IDE) # G240166. Data from this clinical study are the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between December 6, 2024 and April 22, 2026. The database reflected data collected through April 28, 2026 and included 52 patients (50 pivotal and 2 roll-in patients) at 11 investigational sites.

The study was a multicenter, single-arm, prospective clinical investigation to evaluate the safety and effectiveness of the CGuard Prime TransCarotid Stent System (80cm) used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System in patients undergoing carotid artery stenting via the Transcarotid Artery Revascularization (TCAR) approach.

The primary procedural endpoints were acute device success and technical success. Acute device success was defined as successful insertion of the delivery system, successful deployment of the CGuard Prime Carotid Stent, and successful retraction of the delivery system during a TCAR procedure when used in conjunction with the ENROUTE Transcarotid Neuroprotection System. Technical success was defined as the proportion of patients with at least one CGuard Prime TransCarotid Stent System, device successfully delivered and deployed with final residual diameter stenosis <30% following final post-balloon dilation (if performed)..

Secondary endpoints evaluated 30-day clinical outcomes, including hierarchical death, stroke, or myocardial infarction (DSMI), hierarchical death or stroke, and individual rates of death, stroke (major and minor), and myocardial infarction. Secondary endpoints also evaluated stent thrombosis or occlusion within 30 days and through 1 year, device-related serious adverse events within 30 days and through 1 year, and ipsilateral stroke between 31-36 days post index procedure.

Analysis populations included Intent-to-Treat (ITT), Per-Protocol (PP), and Roll-In (RI). The ITT analysis population included all enrolled subjects who provided informed consent, met all eligibility criteria, were approved by the screening committee, and in whom the CGuard Prime TransCarotid Stent System was advanced beyond the arterial sheath. The PP population was the primary analysis population and consisted of a subset of the ITT population who were implanted with the CGuard Prime Carotid Stent at the target lesion, had no major procedural protocol deviations, and had follow-up data available. Roll-In subjects were analyzed separately.

All endpoints were analyzed descriptively. Results were summarized using counts and percentages. No formal hypothesis testing was performed.

The Data Safety Monitoring Board (DSMB) reviewed all study safety data on a regular basis and advised on the continuing safety, validity and scientific merit of the study. Serious Adverse Events were adjudicated by an independent Clinical Events Committee (CEC). All vascular imaging required for the study was evaluated and analyzed by an independent core lab.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the C-GUARDIANS II study was limited to patients who met the following inclusion criteria.

   1. Patient is ≥ 18 years and ≤ 82 years of age.
   2. Patient is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements.

3. Patient is diagnosed with carotid artery disease treatable with a Carotid Artery Stent via a Transcarotid Artery Revascularization approach and is either symptomatic or asymptomatic, defined as:

   Symptomatic carotid stenosis ≥ 50%. Symptomatic is defined as amaurosis fugax, transient ischemia attack (TIA) or stroke within the last 6 months ipsilateral to the side of the stenosis, Or
   Asymptomatic carotid stenosis ≥ 80%

4. High Risk condition for CEA: at least one, as shown below:

   Comorbid conditions:

   - Age ≥ 70 (maximum 82 years)
   - Canadian Cardiovascular Society (CCS) angina class 3-4 or unstable angina
   - Congestive Heart Failure (CHF) New York Heart Association (NYHA) class III-IV
   - Left ventricular ejection fraction (LVEF) ≤ 35%
   - Myocardial infarction (MI) ≥ 72 hours and < 6 weeks pre-procedure
   - Multi-vessel coronary artery disease (CAD) (≥ 2 vessels >70% stenosis) and history of angina
   - Chronic Obstructive Pulmonary Disease (COPD) with forced expiratory volume in 1 second (FEV1)<50
   - Permanent contralateral cranial nerve injury/paralysis
   - Restenosis from previous carotid endarterectomy (CEA)
   - Planned coronary artery bypass grafting (CABG) or valve replacement surgery between 31-60 days after carotid artery stenting (CAS).
   - Abdominal aortic aneurysm surgical repair or Endovascular repair is planned between 31 to 60 days after CAS.

   Anatomic conditions:

   - Occlusion of the contralateral common carotid artery (CCA) or internal carotid artery (ICA).
   - Prior radiation treatment to the neck or a radical neck dissection.
   - Severe bilateral ICA stenosis requiring treatment.
   - Target lesion at or above the level of the jaw (C2) or below the clavicle.
   - Severe tandem lesions
   - Inability to extend the neck due to cervical disorders.
   - Laryngeal palsy or laryngectomy.
   - Prior head and neck surgery in the region of the carotid artery.

- Tracheostomy or tracheostoma.
- Spinal immobility of the neck.
- Hostile neck or surgically inaccessible lesion.

5. Target vessel and lesion meet all requirements for the CGuard Prime Carotid Stent:
   - Target lesion location at the carotid bifurcation and/or proximal internal carotid artery (ICA)
   - The diameter at the stent landing zone is between 4.8 mm and 9.0 mm.
   - The target lesion length is ≤ 36 mm and can be covered by a single CGuard Prime Carotid Stent.
   - Patient must have a 5 cm long disease-free segment of the common carotid artery (CCA) measured from the clavicle to the carotid bifurcation, with a minimum vessel diameter of 6 mm suitable for vascular access, sheath insertion, and vessel clamping.

Patients were <u>not</u> permitted to enroll in the CGUARDIANS II study if they met any of the following exclusion criteria:

1. Patient had or will have an interventional procedure or surgery of the carotid, coronary or peripheral arteries within 30 days before or after the index carotid procedure.
2. Patient had or will have open heart surgery or valvular intervention (percutaneous or surgical), or any major operation, within 30 days before or after the index carotid procedure.
3. Vascular anatomy that would preclude safe sheath insertion or deliverability of stent
4. Patient had a previously placed stent in the ipsilateral ICA or CCA.
5. Total occlusion or presence of a "string sign" of the ipsilateral ICA or CCA.
6. Presence of a filling defect of the target lesion.
7. Tandem lesions with ≥ 50% or ≥ 80% diameter stenosis for symptomatic or asymptomatic patients, respectively, which cannot be covered by a single CGuard Prime™ stent.
8. Patient has a stenosis of the innominate artery or proximal CCA requiring revascularization
9. Patient has an open neck stoma.
10. Patient has a history of bleeding diatheses or coagulopathy.
11. Patient has hypercoagulable state.
12. Patient has an alternative source of cerebral embolus, including but not limited to:

a. Chronic atrial fibrillation.

b. Episode(s) of paroxysmal atrial fibrillation within the past 6 months or history of paroxysmal atrial fibrillation requiring chronic anticoagulation.

c. Knowledge of cardiac sources of embolus (e.g. left ventricular aneurysm, intracardiac filling defect, cardiomyopathy, aortic or mitral prosthetic heart valve, calcific aortic stenosis, endocarditis, mitral stenosis, atrial septal defect, atrial septal aneurysm, or left atrial myxoma).

d. Recently (<60 days) implanted heart valve (either surgically or endovascularly) as a known source of emboli as confirmed on echocardiogram,

e. Abnormal angiographic findings: ipsilateral intracranial or extracranial arterial stenosis (as determined by angiography, computed tomography angiography (CTA), or magnetic resonance angiography (MRA) 6 months prior to index procedure) greater in severity than the lesion to be treated; cerebral aneurysm > 5mm; arteriovenous malformation (AVM) of the cerebral vasculature, or other abnormal angiographic findings.

13. Patient has a known sensitivity or allergy to nickel or titanium.
14. Patient has a sensitivity to contrast media that cannot be adequately pre-treated.
15. Patient has a sensitivity to both forms of protocol-acceptable anticoagulation strategies (i.e., both heparin AND Bivalirudin)
16. Patient has a sensitivity to an antiplatelet agent AND all protocol acceptable alternative antiplatelet options
17. Patient has a known intolerance to statins.
18. Patient has a life expectancy of less than 3 years from the date of enrollment as determined by the Wallaert Life Expectancy Scale
19. Patient has malignancy, primary or recurrent, and does not have independent assessment of life expectancy performed by the treating oncologist or an appropriate specialist other than the physician performing TCAR.
20. Patient has an evolving stroke or intracranial hemorrhage, or a history of previous intracranial hemorrhage or brain surgery within the past 12 months.
21. Patient had a recent stroke (≤ 7 days) placing him/her at risk of a hemorrhagic conversion during the index procedure.
22. Patient has a history of a major stroke with a neurologic deficit (National Institutes of Health Stroke Scale (NIHSS) of ≥ 15 or modified Rankin Scale (mRS) ≥3).
23. Patient had a TIA or amaurosis fugax or stroke within 48 hours of the index procedure.
24. Female patient who is pregnant or lactating or is planning to become pregnant.
25. Dementia or other neurologic condition that is likely to confound the neurologic

assessment.

26. Clinical condition that, in the opinion of the investigator, makes endovascular therapy impossible or hazardous.
27. Patient has been previously enrolled in this clinical trial.
28. Patient is likely to be non-compliant with protocol-required follow up or medication in the opinion of the investigator.
29. Patient is currently participating in another clinical trial that has not completed its primary endpoint assessment or that may confound this study results.

2. Follow-up Schedule

All patients were scheduled to return for follow-up examination at 30 days (± 7 days), and 1 year (± 30 days) postoperatively, as shown in **Table 3** below. Adverse events and complications were recorded at all visits.

To determine subject eligibility, a screening committee reviewed imaging data, along with patient medical history, for assessment of inclusion criteria, and approval prior to the study procedure.

The screening committee was comprised of an interdisciplinary team of study investigators with pertinent knowledge in carotid stenting. Prior to a subject being enrolled in the study, the investigational site received confirmation from the screening committee that the subject was eligible to be enrolled.

Table 3: Schedule of Events

Test/Assessment	Screening	Baseline	Index Procedure	Discharge or 96 hours post-procedure	30 Day (±7D) (9)	1-Year (± 30D)	Unscheduled Visit	Early Withdrawal
Study Visit No.	**1**	**2**	**3**	**4**	**5**	**6**	**--**	**--**
Study Consent	X							
Medical History (incl. Wallert Scale)	X							
Concomitant Medications	X	X	X	X	X	X	X (7)	X (8)
Targeted Physical Exam	X (1)			X	X	X	X (7)	X (8)
Cranial nerve palsy assessment			X	X	X	X		
National Institutes of Health Stroke Scale (NIHSS) (2)		X		X	X	X	X (7)	X (8)
Modified Rankin Scale (mRS)	X (1)			X	X	X	X (7)	X (8)
Carotid Duplex Ultrasound	X (3)				X	X	X (7)	X (8)
CTA, MRA, or catheter angiography	X (4)		X					
12-lead electrocardiogram (ECG)	X (1)			X				
Complete Blood Count	X (1)			X				
Coagulation Panel international normalized ratio (INR) for patients on vitamin K antagonist (VKA)	X (1)			X	X	X	X (7)	X (8)
Chemistry Panel (blood urea nitrogen (BUN), Creatinine)	X (1)							
Cardiac Biomarkers (troponins or creatine kinase - myocardial band (CK-MB))		X		X (5)				
Pregnancy Test (only for females of child-bearing potential) (6)		X						
Adverse Events	X	X	X	X	X	X	X	X

(1) Could be obtained at either Screening or Baseline visit.
(2) Neurological assessment must be performed by a physician or other study team personnel certified in administration of NIHSS.
(3) Bilateral carotid duplex ultrasound was required within 180 days of the procedure. The pre-procedure ultrasound was NOT sent to the core lab.
(4) CTA, MRA or catheter angiography (visualization of vasculature from arch origin to Circle of Willis) was required within 180 days prior to the procedure.
(5) Routine collection for all patients at approximately the following post-index procedure intervals: 12-24 hours, 36-48 hours, 72 hours or at discharge. Thereafter, if cardiac biomarkers remained elevated, collected daily until values showed a decline.
(6) Urine or serum pregnancy test was acceptable.
(7) To be performed as clinically indicated.
(8) Test/assessments to be performed to the extent possible.
(9) If the CGuard Prime TransCarotid Stent System entered the vasculature and was unsuccessful, a telephone follow-up visit was required at 30 days (±7 days).

3. Study Endpoints

Primary Endpoint

The two primary procedural endpoints were as follows:

Acute device success: Successful insertion of the delivery system, successful deployment of the CGuard Prime Carotid Stent, and successful retraction of the delivery system when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

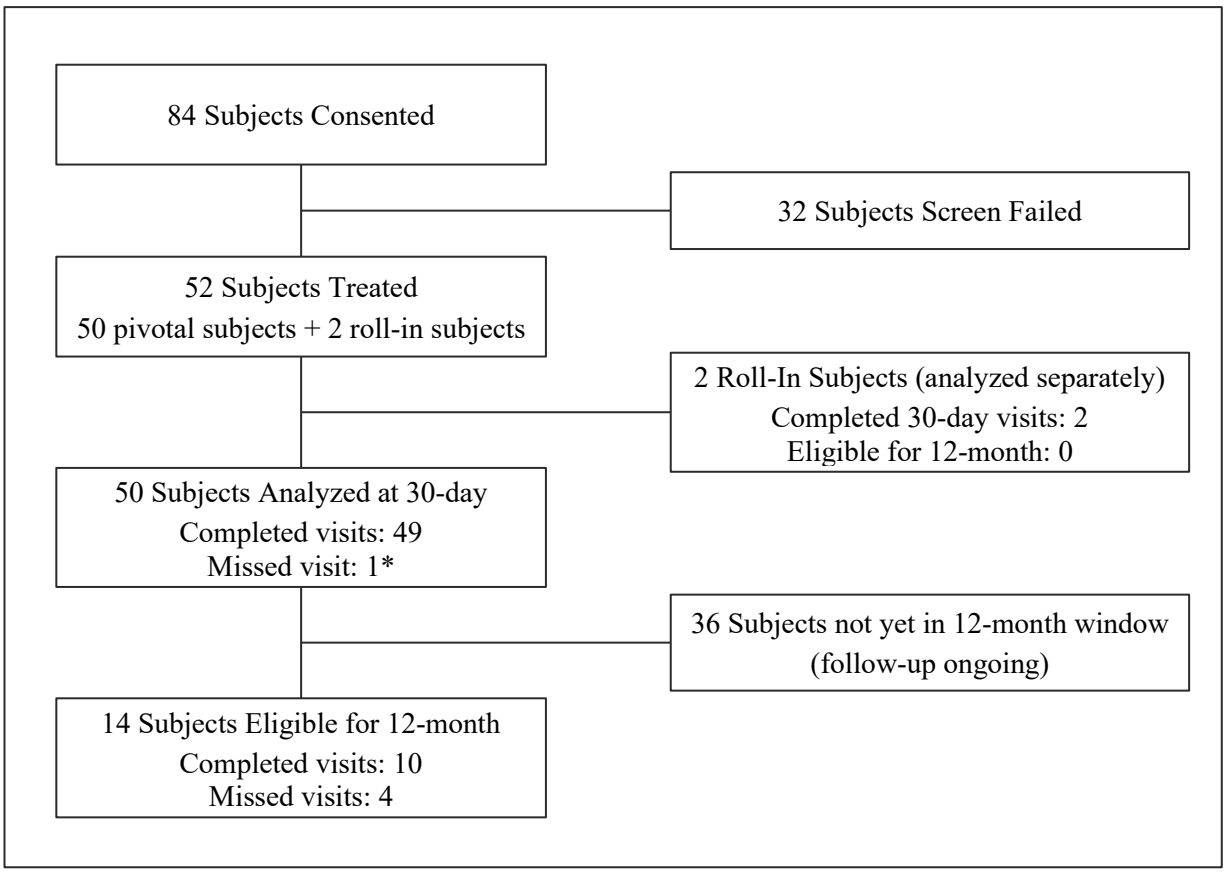
Technical success: Technical Success Rate is defined as the number of patients with at least one CGuard Prime TransCarotid Stent System device successfully delivered and deployed with final residual diameter stenosis < 30% following final post-balloon dilatation (if performed) divided by the total number of patients where CGuard Prime TransCarotid Stent System deployment was attempted when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

Secondary Endpoints included the following:

1. Hierarchical Death, Stroke or Myocardial Infarction (DSMI) within 30 days of the procedure
2. Hierarchical Death or Stroke rate within 30 days of the procedure
3. Rate of death within 30 days of the procedure
4. Rate of all strokes within 30 days of the procedure
5. Rate of major stroke within 30 days of the procedure
6. Rate of minor stroke within 30 days of the procedure
7. Rate of MI within 30 days of the procedure
8. Rate of stent thrombosis or occlusion within 30 days of the index procedure
9. Rate of stent thrombosis or occlusion through 1-year of the index procedure
10. All device-related serious adverse events within 30 days of the procedure
11. All device-related serious adverse events through 1-year of the procedure
12. Rate of ipsilateral strokes between 31- and 365-day post index procedure
13. Procedural Success: defined as number of patients who meet Acute Device Success for the CGuard Prime TransCarotid Stent System without experiencing death, stroke or MI through 30-day post-procedure when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.
14. Treatment Success Rate: defined as the number of patients who meet CGuard Prime TransCarotid Stent System Technical Success without experiencing death, stroke, or MI through 30-day post-procedure, divided by the total number of patients where CGuard Prime TransCarotid Stent System device deployment was attempted when used in conjunction with the FDA-cleared ENROUTE Transcarotid Neuroprotection System during a TCAR procedure.

B. Accountability of PMA Cohort

A summary of subject disposition per ITT analysis is presented in **Figure 3**.



* One subject completed the 30-day carotid duplex ultrasound but did not complete all other protocol-required 30-day assessments; the subject was retained in the 30-day analysis.

Figure 3: Subject Disposition per ITT Analysis

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a carotid artery stenting study performed in the US.

Table 4 presents demographic and lifestyle factors, race/ethnicity, baseline neurologic scales, and symptomatology, characterizing the 50 subjects in the PP population. The mean age was 69.7 ± 6.6 years (median 70.0 years; range 54–82), and 62.0% of subjects were male. Cardiovascular risk factors were common, including a history of smoking in 72.0% of subjects and current alcohol use in 26.0%. Baseline neurologic status was favorable, with 91.5% of subjects scoring 0 on the NIH Stroke Scale and 89.3% scoring 0 on the modified Rankin Scale. The majority of subjects (76.0%) were asymptomatic, defined as having no history of ipsilateral symptoms (stroke, TIA, or amaurosis fugax) within 180 days prior to the index procedure.

Table 4: Subject Demographics

Demographics (by patient)	PP N=50* n, (n/N%)
Age(years)	50
Mean ± SD	69.7 ± 6.6
Median [IQR]	70.0 [64.0, 74.0]
(Range)	(54, 82)
Gender	50
Male	31 (62.0%)
Female	19 (38.0%)
Race	50
American Indian or Alaska Native	1 (2.0%)
Asian	1 (2.0%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)
Black or African American	3 (6.0%)
White	42 (84.0%)
Unknown or not reported	3 (6.0%)
Ethnicity	50
Hispanic or Latino	3 (6.0%)
Not Hispanic or Latino	41 (82.0%)
Unknown or Not Reported	6 (12.0%)
Current Alcohol Use(Yes), n(%)	13 (26.0%)
Smoking History(Yes), n(%)	36 (72.0%)
Years Smoked	33
Mean ± SD	29.7 ± 15.41
Median [IQR]	30.0 [20.0, 44.0]
(Range)	(0, 56)
Total Packs Year	31
Mean ± SD	30.0 ± 19.46
Median [IQR]	25.0 [14.0, 44.0]
(Range)	(4, 90)
NIH Stroke Scale Total Score	47
0	43 (91.5%)
1	2 (4.3%)
2	1 (2.1%)
3	0 (0.0%)
4	1 (2.1%)
Modified Rankin Scale (mRS Score)	28
0	25 (89.3%)
1	3 (10.7%)
2	0 (0.0%)
Symptomatic/Asymptomatic	50
Asymptomatic	38 (76.0%)
Symptomatic	12 (24.0%)
* Percentages are calculated using the number of patients (N) with available data for that category. N=50 unless otherwise noted.	

Table 5 enumerates cardiovascular, neurologic, pulmonary, metabolic, and other relevant comorbidities at baseline to contextualize patient risk. Hypertension was the most common condition, reported in 94.0% of subjects, followed by hypercholesterolemia/dyslipidemia in 86.0%, and diabetes mellitus in 44.0%. Coronary artery disease was also present in 44.0%, with 16% having a prior percutaneous coronary intervention (PCI) and 20.0% a history of myocardial infarction. Cerebrovascular history was also significant: 30.0% of subjects had a previous stroke, and 12.0% had experienced a transient ischemic attack. Additional relevant comorbidities included chronic obstructive pulmonary disease (COPD) (14.0%), chronic renal impairment (14.0%), peripheral vascular disease (14.0%), and cancer (20.0%).

Table 5: Subject Medical History

Medical History (by patient)	PP (N=50)
Alzheimer Disease, n(%)	1 (2.0%)
Diabetes Mellitus, n(%)	22 (44.0%)
Non-Alzheimer Dementia, n(%)	1 (2.0%)
Depression, n(%)	10 (20.0%)
Angina, n(%)	7 (14.0%)
Cardiac Arrythmia, n(%)	1 (2.0%)
Atrial Fibrillation, n(%)	0 (0.0%)
Congestive Heart Failure, n(%)	3 (6.0%)
Coagulopathy, n(%)	0 (0.0%)
COPD, n(%)	7 (14.0%)
FEV1 <50, n(%)	0 (0.0%)
Congenital Heart Disease, n(%)	0 (0.0%)
Coronary Artery Disease, n(%)	22 (44.0%)
Previous PCI, n(%)	8 (16.0%)
Previous Carotid Intervention, n(%)	6 (12.0%)
GI/GU Bleeding, n(%)	1 (2.0%)
Chronic Renal Impairment, n(%)	7 (14.0%)
Hypercholesterolemia/Dyslipidemia, n(%)	43 (86.0%)
Hypertension, n(%)	47 (94.0%)
Hypotension, n(%)	1 (2.0%)
Peripheral Vascular Disease, n(%)	7 (14.0%)
Myocardial Infarction, n(%)	10 (20.0%)
Transient Ischemic Attack, n(%)	6 (12.0%)
Stroke, n(%)	15 (30.0%)
Amaurosis Fugax, n(%)	1 (2.0%)
Cancer, n(%)	10 (20.0%)
Heart Conduction Troubles, n(%)	0 (0.0%)
Other Medical History, n(%)	25 (50.0%)

Table 6 captures the procedural parameters (procedure time, pre/post-dilatation details, anticoagulation, activated clotting time (ACT) measurement) and immediate angiographic results (e.g., dissections). The mean procedure duration was 90.5 ± 39.43 minutes. All subjects (100%) had successful advancement, deployment, and retrieval of the CGuard Prime TransCarotid Stent System. Pre-dilatation was performed in all 50 subjects.

Post-dilatation was performed in 84.0% of cases, including the subject who did not meet the criterion for Technical Success (final residual diameter stenosis of 31%).
Protamine was administered in 93.9% of subjects, and ACT was measured in 98.0% of procedures. All procedures included radiation, contrast, and anticoagulation.

Table 6: Procedural Characteristics (Site Reported)

Procedural Parameters	PP (N=50)
Procedure time(mins)	
N	50
Mean ± SD	90.5 ± 39.43
Median [IQR]	80.0 [64.0, 108.0]
(Range)	(41, 207)
CGuard Prime TransCarotid Stent System advanced beyond the arterial sheath, n (n/N%)	50 (100.0%)
CGuard Prime TransCarotid Stent System Stent Deployed, n (n/N%)	50 (100.0%)
CGuard Prime TransCarotid Stent System Delivery System Retrieved, n (n/N%)	50 (100.0%)
Second stent used, n (n/N%)	1 (2.0%)*
Radiation used, n (n/N%)	50 (100.0%)
Contrast used, n (n/N%)	49 (100.0%)**
Anticoagulation medication used, n (n/N%)	50 (100.0%)
ACT measured, n (n/N%)	49 (98.0%)
Protamine used, n (n/N%)	46 (93.9%)
Pre-dilatation performed, n (n/N%)	50 (100.0%)
Dissection after Pre-dilatation, n (n/N%)	0 (0.0%)
Post-dilatation performed, n (n/N%)	42 (84.0%)
Dissection after Post-dilatation, n (n/N%)	0 (0.0%)
* In one subject, a second stent was placed for complete lesion coverage ** One value for the contrast used was missing; therefore, percentages were calculated based on non-missing values	

Table 7 summarizes lesion type, location, morphology, calcification, reference diameters, and pre/post-stenosis (site-assessed), as well as vessel tortuosity and arch type. The treated lesions were predominantly de novo, reported in 98.0% of subjects, with only 1 case (2.0%) of re-stenotic CEA. Lesion location was mainly within the internal carotid artery (ICA) (78.0%), while 22.0% involved the carotid bifurcation. Morphologically, lesions were primarily eccentric (67.3%), with ulceration present in 20.4% and thrombus noted in 10.2% of cases. Vessel tortuosity was mostly mild (58.0%) or absent (22.0%).

Table 7: Lesion Characteristics (Site Reported)

Target Lesion Parameters	PP (N=50)
Target Lesion, n(%)	
De novo	49 (98.0%)
Re-stenotic CEA	1 (2.0%)
Target Lesion (Location), n(%)	
ICA	39 (78.0%)
Bifurcation	11 (22.0%)
Target Lesion Characteristics*	
Eccentric	33 (67.3%)
Concentric	11 (22.4%)
Ulceration	10 (20.4%)
Thrombus present in lesion	5 (10.2%)
None	0 (0.0%)
Target Lesion Assessed by, n(%)	
Quantitative Angiography	45 (90.0%)
Other	5 (10.0%)
Vessel Tortuosity, n(%)	
None	11 (22.0%)
Mild	29 (58.0%)
Moderate	7 (14.0%)
Severe	3 (6.0%)
Stent Diameter at Narrowest point (mm)	
Mean ± SD	4.9 ± 0.99
Median [IQR]	4.9 [4.5, 5.1]
(Range)	(3, 10)
Arch Type, n(%)**	48
Type I	23 (47.9%)
Type II	15 (31.3%)
Type III	5 (10.4%)
Bovine	5 (10.4%)
* Not mutually exclusive ** Two subjects had multiple Arch Type values recorded in the electronic data capture (EDC) system and were excluded from the Arch Type summary.	

Table 8 provides core-lab quantitative angiography for lesion length, lumen diameters, calcification, and pre/post-intervention stenosis to support performance outcomes. Core laboratory analysis confirmed the angiographic severity and morphology of the treated lesions prior to intervention. Mean lesion length was approximately 12 mm, with a minimum lumen diameter of 1.6 mm and reference lumen diameter of 4.2 mm. Moderate or severe calcification was present in

89.6% of lesions. Mean pre-procedure diameter stenosis was 84.5 ± 12.0%. Following treatment, residual diameter stenosis was reduced to 5.3 ± 8.3%, with a post-procedure minimum lumen diameter of 4.4 mm.

Table 8: Lesion Characteristics (Core Lab Reported*)

Parameter	PP (N=50)**
Pre-intervention	
Lesion Length (mm), N	49
Mean ± SD	12.1 ± 5.5
Median [IQR]	11.0 [8.0, 15.0]
Range	(3.9, 29.0)
Minimum Lumen Diameter (mm), N	49
Mean ± SD	1.6 ± 0.7
Median [IQR]	1.5 [1.0, 1.9]
Range	(0.2, 4.1)
Reference Lumen Diameter (mm), N	49
Mean ± SD	4.2 ± 0.8
Median [IQR]	4.1 [3.7, 4.8]
Range	(2.9, 6.0)
Calcification, N	48
None/Mild	5 (10.4%)
Moderate	21 (43.8%)
Severe	22 (45.8%)
Average Percent Diameter Stenosis (%), N	45
Mean ± SD	84.5 ± 12.0
Median [IQR]	88.0 [81.0, 91.0]
Range	(40.0, 99.0)
CCA Reference Lumen Diameter (mm), N	49
Mean ± SD	6.9 ± 1.4
Median [IQR]	6.6 [5.9, 8.1]
Range	(3.9, 9.8)
Post-Intervention	
Minimum Lumen Diameter (mm), N	48
Mean ± SD	4.3 ± 0.9
Median [IQR]	4.2 [3.7, 5.0]
Range	(2.8, 6.4)
Average Percent Diameter Stenosis (%), N	46
Mean ± SD	5.3 ± 8.3
Median [IQR]	0.0 [0.0, 9.0]
Range	(0.0, 31.0)

* Measurements represent the core laboratory assessment from the angiographic projection providing the optimal visualization of the target lesion. When multiple projections were available, the view demonstrating the most severe lesion characteristics was utilized for summary reporting.
** N varies as noted for each parameter and results are presented based on data available.

D. Safety and Effectiveness Results

1. Primary Endpoint Results

Table 9 reports acute device and technical success. Acute Device Success was achieved in all 50 subjects (100%). Technical Success was achieved in 49 of 50 evaluable subjects (98.0%). One subject did not meet the criteria for Technical Success, as the core laboratory reported final residual diameter stenosis was 31%, and therefore did not meet the definition of Technical Success (final residual diameter stenosis < 30%).

Table 9: Primary Procedural Endpoints

Endpoint	Subjects n/N (%)
Acute Device Success	50/50 (100.00%)
Technical Success	49/50 (98.00%)

2. Secondary Endpoint Results

Secondary endpoint results were descriptive in nature without any formal statistical hypotheses testing.

Across all secondary clinical endpoints evaluated at 30 days, no subjects experienced an event. Death, stroke, myocardial infarction, and stent thrombosis within 30 days following the procedure were all 0/50 (0%).

Secondary procedural endpoints mirrored the primary results. Procedural Success was achieved in 50/50 subjects (100.0%). Treatment Success, defined using core-laboratory or investigator-reported residual stenosis when core-laboratory data were missing, was achieved in 49/50 subjects (98.0%). Further details are presented in **Table 10**.

Table 10: Secondary Procedural Endpoints

Endpoint	Subjects n/N (%)
Procedural Success	50/50 (100.00%)
Treatment Success	49/50 (98.00%)

Follow-up to the 1-year timepoint continues and secondary endpoints evaluated at 1-year will be assessed in the continued follow-up post-approval study.

3. Adverse Events

An Adverse Event (AE) was defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated. (ISO 14155:2020)

A Serious Adverse Event (SAE) was defined as an Adverse Event that led to any of the following:

1. Death
2. Serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:
    a. a life-threatening illness or injury
    b. a permanent impairment of a body structure or a body function, including chronic disease, or
    c. the prolongation of an existing hospitalization, or
    d. Resulted in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to body structure or a body function, fetal distress, fetal death, a congenital abnormality, or birth defect including physical or mental impairment. (ISO 14155:2020).

A planned hospitalization for a pre-existing condition was not considered an SAE. An Adverse Device Effect (ADE) was defined as an Adverse Event related to use of an investigational medical device as defined by ISO 14155:2020 and adjudicated by the CEC.

Table 11 provides 0–30 days AE incidence, including procedure- and device-relatedness and seriousness, with subject counts and total events. Across the ITT population (N=50), 22 subjects (44.0%) experienced 33 adverse events during the first 30 days of the study. Two device-related adverse events were reported in two subjects (4.0%). Procedure-related adverse events were reported in 15 subjects (30.0%), representing 21 events.

Table 11: Summary of All AEs

	ITT (N=50)	
	0-30 Days	
Adverse Event Category	**Subjects n/N (%)**	**Number of Events**
All Adverse Events	22/50 (44.0%)	33
Device Related	2/50 (4.0%)	2
Procedure Related	15/50 (30.0%)	21
Serious Adverse Events	6/50 (12.0%)	9
Device Related	2/50 (4.0%)	2
Procedure Related	5/50 (10.0%)	6
Non-Serious Adverse Events	18/50 (36.0%)	24
Device Related	0/50 (0.0%)	0
Procedure Related	12/50 (24.0%)	15
Note: Two adverse events have a missing onset date and are not included in the table.		

Serious adverse events occurred in 6 subjects (12.0%), totaling 9 events. Two serious adverse events were device-related, and no serious adverse events resulted in death. Serious adverse events are summarized by System Organ Class and Preferred Term in **Table 12**.

Table 12: Serious Adverse Event Summary

	ITT (N=50)		PP (N=50)	
Serious Adverse Events	**Subjects* n(n/N%)**	**Events N**	**Subjects* n(n/N%)**	**Events N**
Infections and infestations	2 (4.0%)	4	2 (4.0%)	4
Bacteremia	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Gastroenteritis	1 (2.0%)	1	1 (2.0%)	1
Pyelonephritis acute	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Hemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	3 (6.0%)	3	3 (6.0%)	3
Hypotension	2 (4.0%)	2	2 (4.0%)	2
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

* Subjects may have more than one event and will be counted once in each category for which they had an event.
Note: Adverse Events are classified by Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) and Preferred Term (PT).

Non-serious AEs were reported in 18 subjects (36.0%), totaling 24 events. The most represented SOC categories included vascular disorders (8.0%), musculoskeletal/connective tissue disorders (6.0%), respiratory disorders (4.0%), infections (4.0%), nervous system disorders (4.0%) and skin and subcutaneous tissue disorders (4.0%). No non-serious AEs were attributed to the study device. Further details are presented in the following **Table 13**.

Following the data-cut off on April 20, 2026, a potential additional adverse event was discovered through a monitoring visit, which had not been previously reported. A subject with extensive cardiovascular disease and prior left hemispheric strokes underwent the index procedure, remained neurologically stable, and was discharged 5 days later to an inpatient rehabilitation facility due to persistent functional deficits and high fall risk related to pre-existing conditions. The event was not deemed to be related by the device or procedure by the site. The event did not meet the criteria for CEC adjudication.

Table 13: Non-Serious Adverse Event Summary

	ITT (N=50)		PP (N=50)	
Non-Serious Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Blood and lymphatic system disorders	1 (2.0%)	1	1 (2.0%)	1
Normocytic anemia	1 (2.0%)	1	1 (2.0%)	1
Cardiac disorders	1 (2.0%)	1	1 (2.0%)	1
Bradycardia	1 (2.0%)	1	1 (2.0%)	1
Endocrine disorders	1 (2.0%)	1	1 (2.0%)	1
Diabetic neuropathy	1 (2.0%)	1	1 (2.0%)	1
Eye disorders	1 (2.0%)	1	1 (2.0%)	1
Visual impairment	1 (2.0%)	1	1 (2.0%)	1
Gastrointestinal disorders	1 (2.0%)	1	1 (2.0%)	1
Gastroesophageal reflux disease	1 (2.0%)	1	1 (2.0%)	1
Infections and infestations	2 (4.0%)	2	2 (4.0%)	2
Upper respiratory tract infection	2 (4.0%)	2	2 (4.0%)	2
Injury, poisoning and procedural complications	2 (4.0%)	2	2 (4.0%)	2
Urinary retention postoperative	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Musculoskeletal and connective tissue disorders	3 (6.0%)	3	3 (6.0%)	3
Back pain	2 (4.0%)	2	2 (4.0%)	2
Arthralgia	1 (2.0%)	1	1 (2.0%)	1
Nervous system disorders	2 (4.0%)	2	2 (4.0%)	2
Essential tremor	1 (2.0%)	1	1 (2.0%)	1
Vertigo positional	1 (2.0%)	1	1 (2.0%)	1
Psychiatric disorders	1 (2.0%)	1	1 (2.0%)	1
Anxiety	1 (2.0%)	1	1 (2.0%)	1
Renal and urinary disorders	1 (2.0%)	1	1 (2.0%)	1
Urinary retention	1 (2.0%)	1	1 (2.0%)	1
Reproductive system and breast disorders	1 (2.0%)	1	1 (2.0%)	1
Benign prostatic hyperplasia	1 (2.0%)	1	1 (2.0%)	1
Respiratory, thoracic and mediastinal disorders	2 (4.0%)	2	2 (4.0%)	2
Dyspnea	1 (2.0%)	1	1 (2.0%)	1
Epistaxis	1 (2.0%)	1	1 (2.0%)	1
Skin and subcutaneous tissue disorders	2 (4.0%)	2	2 (4.0%)	2
Rash	2 (4.0%)	2	2 (4.0%)	2

	ITT (N=50)		PP (N=50)	
Non-Serious Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Surgical and medical procedures	1 (2.0%)	1	1 (2.0%)	1
Incisional drainage	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	4 (8.0%)	4	4 (8.0%)	4
Hypotension	2 (4.0%)	2	2 (4.0%)	2
Hematoma	1 (2.0%)	1	1 (2.0%)	1
Hypertension	1 (2.0%)	1	1 (2.0%)	1
* Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

Device Related Adverse Events occurred in two subjects (4.0%), with two events of hypotension reported. These events were classified as serious and resolved with appropriate medical management within 1 and 2 days, respectively.

Table 14 details Device Related Adverse Events and, **Table 15** details Serious Device Related Adverse Events, with subject and event counts.

Table 14: Device Related Adverse Events

	ITT (N=50)		PP (N=50)	
All Device Related Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Vascular disorders	2 (4.0%)	2	2 (4.0%)	2
Hypotension	2 (4.0%)	2	2 (4.0%)	2
*Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

Table 15: Serious Device Related Adverse Events

	ITT (N=50)		PP (N=50)	
All Device Related Serious Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Vascular disorders	2 (4.0%)	2	2 (4.0%)	2
Hypotension	2 (4.0%)	2	2 (4.0%)	2
* Subjects may have more than one event and will be counted once in each category for which they had an event. Note: Adverse Events are classified by MedDRA SOC and Preferred Term.				

Procedure-related events occurred in 15 subjects (30%), with 21 events reported. These included vascular access site swelling (4.0%), urinary retention (2.0%), visual impairment (2.0%), and transient respiratory (4.0%) or musculoskeletal symptoms (2.0%). No single event type occurred at a concerning frequency. **Table 16**, below, details procedure-related AEs by SOC/PT with subject and event counts.

Table 16: Procedure Related Adverse Events

	ITT (N=50)		PP (N=50)	
Procedure Related Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Blood and lymphatic system disorders	1 (2.0%)	1	1 (2.0%)	1
Normocytic anemia	1 (2.0%)	1	1 (2.0%)	1
Cardiac disorders	1 (2.0%)	1	1 (2.0%)	1
Bradycardia	1 (2.0%)	1	1 (2.0%)	1
Eye disorders	1 (2.0%)	1	1 (2.0%)	1
Visual impairment	1 (2.0%)	1	1 (2.0%)	1
Infections and infestations	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	3 (6.0%)	3	3 (6.0%)	3
Vascular access site swelling	2 (4.0%)	2	2 (4.0%)	2
Urinary retention postoperative	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Hemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1
Musculoskeletal and connective tissue disorders	1 (2.0%)	1	1 (2.0%)	1
Arthralgia	1 (2.0%)	1	1 (2.0%)	1
Renal and urinary disorders	1 (2.0%)	1	1 (2.0%)	1
Urinary retention	1 (2.0%)	1	1 (2.0%)	1
Reproductive system and breast disorders	1 (2.0%)	1	1 (2.0%)	1
Benign prostatic hyperplasia	1 (2.0%)	1	1 (2.0%)	1
Respiratory, thoracic and mediastinal disorders	2 (4.0%)	2	2 (4.0%)	2
Dyspnea	1 (2.0%)	1	1 (2.0%)	1
Epistaxis**	1 (2.0%)	1	1 (2.0%)	1
Skin and subcutaneous tissue disorders	2 (4.0%)	2	2 (4.0%)	2
Rash	2 (4.0%)	2	2 (4.0%)	2
Surgical and medical procedures	1 (2.0%)	1	1 (2.0%)	1
Incisional drainage	1 (2.0%)	1	1 (2.0%)	1

	ITT (N=50)		PP (N=50)	
Procedure Related Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Vascular disorders	6 (12.0%)	6	6 (12.0%)	6
Hypotension	4 (8.0%)	4	4 (8.0%)	4
Hypertension	1 (2.0%)	1	1 (2.0%)	1
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

* Subjects may have more than one event and will be counted once in each category for which they had an event.

** The onset date for Adverse Event No. 3 in Subject CGII-04-001 was missing; therefore, this adverse event was not included in the total count (see Table 15, Overall Adverse Event Summary) but is reported here for completeness.

Note: Adverse Events are classified by MedDRA SOC and Preferred Term

Serious procedure-related events were rare, occurring in 5 subjects (10.0%), with 6 total events, as detailed in **Table 17**, below.

All events were non-fatal, resolved with appropriate medical management, and occurred exclusively in the early post-procedure period. Importantly, no serious procedure-related strokes or myocardial infarctions were reported.

Table 17: Serious Procedure Related Adverse Events

	ITT (N=50)		PP (N=50)	
Procedure Related Serious Adverse Events	**Subjects* n(n/N%)**	**Events**	**Subjects* n(n/N%)**	**Events**
Infections and infestations	1 (2.0%)	1	1 (2.0%)	1
Clostridium difficile colitis	1 (2.0%)	1	1 (2.0%)	1
Injury, poisoning and procedural complications	1 (2.0%)	1	1 (2.0%)	1
Vascular access site swelling	1 (2.0%)	1	1 (2.0%)	1
Investigations	1 (2.0%)	1	1 (2.0%)	1
Hemoglobin decreased	1 (2.0%)	1	1 (2.0%)	1
Vascular disorders	3 (6.0%)	3	3 (6.0%)	3
Hypotension	2 (4.0%)	2	2 (4.0%)	2
Hypertensive urgency	1 (2.0%)	1	1 (2.0%)	1

*Subjects may have more than one event and will be counted once in each category for which they had an event.

Note: Adverse Events are classified by MedDRA SOC and Preferred Term

Secondary Safety Endpoints were consistent with the primary safety results. Two Serious Device-Related Adverse Events occurred within 30 days of the procedure in two subjects (4.0%). Both events were hypotension; one was assessed by the investigator as probably related and one as possibly related to the device. Both events resolved with appropriate medical management within 1 and 2 days, respectively

Table 18: Serious Device Related Adverse Events within 30 Days of Procedure

Endpoint	Number of Events	Number of Subjects n (%)
Serious Adverse Device Effect (SADE) within 30 days of procedure	2	2 (4.00%)
Causally Related	0	0 (0%)
Probably Related	1	1 (2.00%)
Possibly Related	1	1 (2.00%)
Type of SADE		
Vascular disorders	2	2 (4.0%)
Hypotension	2	2 (4.0%)

4. Subgroup Analyses

Table 19 reports subgroup analyses of Acute Device Success and Technical Success by symptomatic status and age (< 71 years and ≥ 71 years), respectively.

Acute Device Success was achieved in all 38 asymptomatic subjects (100.0%) and all 12 symptomatic subjects (100.0%), while Technical Success was achieved in 37 of 38 asymptomatic subjects (97.37%) and in all symptomatic subjects (100.0%). In the age subgroup analysis, Acute Device Success was achieved in all 26 subjects aged <71 years (100.0%) and in all 24 subjects aged ≥71 years (100.0%). Technical Success was achieved in all subjects aged <71 years (100.0%) and in 23 of 24 subjects aged ≥71 years (95.83%).

Table 19: Primary Procedural Endpoints – Subgroup Analyses

Subgroup		Endpoint, n/N (%)	
		Acute Device Success	Technical Success
Symptomatic Status	Asymptomatic	38/38 (100.00%)	37/38 (97.37%)
	Symptomatic	12/12 (100.00%)	12/12 (100.00%)
Age	Age <71 years	26/26 (100%)	26/26 (100%)
	Age ≥71 years	24/24 (100%)	23/24 (95.83%)

5. Pediatric Extrapolation

In this premarket application, existing clinical data were not leveraged to support approval of a pediatric patient population.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 32 investigators; none were employees of the sponsor, and three had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 3
- Significant payment of other sorts: 0
- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 1

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Safety and Effectiveness Conclusions

The risks of the device are based on non-clinical laboratory as well as data collected in a clinical study conducted to support PMA approval as described above. Non-clinical testing performed during the design and development of the CGuard Prime TransCarotid Stent System confirmed the product design characteristics, specifications, and intended use. The non-clinical engineering testing conducted on the stent and delivery system demonstrated that the performance characteristics met the product specifications. The shelf-life testing has established acceptable performance for a labeled shelf life up to 2 years.

A prospective, multicenter, single arm study (CGUARDIANS II) was conducted to support approval of this device. The findings of this study from the 50 pivotal subjects enrolled demonstrate that the CGuard Prime TransCarotid Stent System achieved the following:

- Primary and secondary procedural endpoints demonstrated 100% acute device and procedural success and 98% technical and treatment success. Subgroup analyses by symptomatic status and age were consistent with the overall Primary Procedural Endpoints.

- 30-day clinical safety endpoints showed no deaths, strokes, myocardial infarctions, stent thrombosis, and two serious device-related adverse events.
- Duplex ultrasound confirmed 100% of stents were patent at 30 days, with no evidence of thrombosis.
- The device performed similarly across diverse anatomical and lesion characteristics, including predominantly de novo lesions and significant baseline stenosis.
- Adverse events, though common in a high-risk vascular population, were manageable, largely non-device-related (with only two exceptions), and did not compromise the clinical endpoints.
- Protocol deviations did not meaningfully impact data integrity or endpoint evaluation. Only one device deficiency was reported in this study, which required no corrective intervention and was not associated with any adverse event.

Overall, the data on the 50 subjects provide evidence that the CGuard Prime TransCarotid Stent System, when used in conjunction with the ENROUTE Transcarotid Neuroprotection System, is shown to be a safe and effective method for treating patients at high risk for adverse events from carotid endarterectomy.

B. Benefit-Risk Determination

The probable benefits of the device are based on data collected in the CGUARDIANS II clinical study conducted to support PMA approval as described above. The CGUARDIANS II trial has established the safety and effectiveness of the CGuard Prime TransCarotid Stent System, and the results are in alignment with other approved carotid stents.

In conclusion, given the available information, the data support that for the treatment of carotid artery stenosis in patients deemed at high surgical risk for carotid endarterectomy, the overall benefits of using the CGuard Prime TransCarotid Stent System outweigh the overall risks.

1. Patient Perspective

   This submission did not include specific information on patient perspectives for this device.

C. Overall Conclusions

The clinical and non-clinical data in this application support a reasonable assurance that the device is safe and effective when used in accordance with the indications for use. The clinical study results were in alignment with other approved carotid stent systems. Therefore, it is reasonable to conclude that the benefits of use of the device for the target population outweigh the risk of illness or injury when used as indicated in accordance with the labeling and Instructions for Use (IFU).

D. CDRH DECISION

CDRH issued an approval order on November 9, 2026. The final conditions of approval cited in the approval order are described below.

Post-Approval Study – Continued Follow-up Study. This study should be conducted per CGUARDIANS II Trial Protocol Number 4 (dated October 28, 2025). This study is a prospective, multicenter follow-up of the pivotal study (G240166) that treated 52 subjects from 11 investigational sites. It will evaluate the long-term safety and effectiveness of the CGuard Prime TransCarotid Stent System. All 42 remaining subjects active at the end of the 30-day evaluation will continue to be followed through 12 months. Follow-up at the 12-month timepoint will include the following: an assessment of concomitant medications (anticoagulant and/or antiplatelet), physical exam, NIH Stroke Scale, modified Rankin Scale, cranial nerve palsy assessment, carotid duplex ultrasound, INR for patients on long term VKA anticoagulant therapy, and adverse event assessment.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality Management System Regulation (QMSR) (21 CFR 820).

E. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.