DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

November 10, 2016

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Jennifer Correa
Sr. Regulatory Affairs Product Specialist
9775 Toledo Way
Irvine, California 92618

Re: K162539
Trade/Device Name: Solitaire 2 Revascularization Device
Regulation Number: 21 CFR 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment
Regulatory Class: Class II
Product Code: POL, NRY
Dated: September 9, 2016
Received: September 12, 2016

Dear Ms. Jennifer Correa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162539

Device Name
Solaitaire™ 2 Revascularization Device

Indications for Use *(Describe)*

1. The Solitaire™ 2 Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) Summary **K162539**

510(k) Owner: Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Contact Person: Jennifer Correa
Senior Specialist, Regulatory Affairs
Telephone: (949) 297-9563
E-mail: jennifer.l.correa@medtronic.com

Date Summary Prepared: October 28, 2016

Trade Name of Device: Solitaire™ 2 Revascularization Device

Common Name of Device: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment

Classification of Device: Class II, 21 CFR 882.5600, 21 CFR 870.1250

Product Code: POL, NRY

Predicate Devices: Trevo XP ProVue Retriever
DEN150049

Clinical Data: A global, multicenter, two-arm, prospective, randomized, open, blinded endpoint (PROBE) clinical study (SWIFT PRIME, IDE G120142) comparing neurological disability outcomes (defined by mRS) in Acute Ischemic Stroke (AIS) patients who are treated with either IV t-PA alone or IV t-PA in combination with Solitaire mechanical thrombectomy intervention was performed. The data from the SWIFT PRIME study in comparison to the data from the Trevo clinical study demonstrate that the use of the Solitaire Revascularization device is safe and is substantially equivalent to the predicate device for reducing disability in patients with a persistent proximal anterior circulation large vessel occlusion and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA) for acute ischemic stroke.

Conclusion: The Solitaire™ 2 Revascularization Device is substantially equivalent to the Trevo XP ProVue Retriever based on comparison of the Trevo clinical data to the SWIFT PRIME clinical study data. In addition, the Solitaire™ 2 Revascularization Device is substantially equivalent to the Trevo XP ProVue Retriever in terms of fundamental scientific technology, including similarities in design, principles of operation, and indications for use.

Device Description:
The Solitaire™ 2 Revascularization Device is designed to restore blood flow in patients experiencing ischemic stroke due to large intracranial vessel occlusion. The Solitaire™ 2 Revascularization Device is designed for use in the neurovasculature such as the Internal Carotid Artery (ICA), M1 and M2 segments of the middle cerebral artery, basilar, and the vertebral arteries. The distal nitinol portion of the Solitaire™ 2 Revascularization Device facilitates clot retrieval and has Iridium radiopaque markers on the proximal and distal ends. The devices are supplied sterile and are intended for single-use only.

There have been no changes to the Solitaire™ 2 Revascularization Device from the currently cleared Solitaire devices (K113455, K123378 and K141491) to support the proposed additional indication. Indication for Use #2 is the same indication as the currently cleared Solitaire Devices under product code NRY (K113355, K123378 and K141491). The currently cleared Solitaire™ 2 Revascularization device is used as a reference device for Indication for Use, previously completed bench, animal, and clinical data.

Indications for Use:
1. The Solitaire™ 2 Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset.

2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.

Device Comparison:
The table below provides a comparison of the technological characteristics of the Solitaire™ 2 Revascularization Device and the predicate Trevo XP ProVue Retriever (DEN150049).

	Predicate Device Trevo XP ProVue Retriever (DEN150049)	**Subject Device Solitaire™ 2 Revascularization Device**	**Rationale for Difference (if applicable)**
Indication for Use	The Trevo ProVue and XP ProVue Retrievers are intended to restore blood flow in the neurovascular by removing thrombus for treatment of acute ischemic stroke to reduce disability in patients with	1. The Solitaire™ 2 Revascularization Device is indicated for use to restore blood flow in the neurovasculature by removing thrombus for the treatment of acute ischemic stroke to reduce disability	Indication 1: N/A, same as predicate device Indication 2: N/A, same as reference

	Predicate Device Trevo XP ProVue Retriever (DEN150049)	**Subject Device Solitaire™ 2 Revascularization Device**	**Rationale for Difference (if applicable)**
	a persistent, proximal anterior circulation, large vessel occlusion, and small core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should start within 6 hours of symptom onset.	in patients with a persistent, proximal anterior circulation, large vessel occlusion, and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA). Endovascular therapy with the device should be started within 6 hours of symptom onset. 2. The Solitaire™ Revascularization Device is indicated to restore blood flow by removing thrombus from a large intracranial vessel in patients experiencing ischemic stroke within 8 hours of symptom onset. Patients who are ineligible for IV t-PA or who fail IV t-PA therapy are candidates for treatment.	predicate device (K113455, K123378 and K141491 cleared under product code NRY)
Principles of Operation	The device is used in the neurovasculature to restore blood flow for treatment of acute ischemic stroke	Same	N/A
Dimensions and Materials			
Device Size(s)	3x20 mm 4x20 mm 4x30 mm 6x25 mm	4x15 mm 4x20 mm 4x40 mm 6x20 mm 6x30 mm	Both devices are offered in a variety of sizes designed to be used in the neurovasculature to restore blood flow.
Device Materials	Core Wire Material: Nitinol (nickel titanium alloy)	Stent: Nitinol Pushwire: Nitinol Markers: 90% Platinum/	Both device materials are biocompatible,

	Predicate Device Trevo XP ProVue Retriever (DEN150049)	**Subject Device Solitaire™ 2 Revascularization Device**	**Rationale for Difference (if applicable)**
	Distal Shaped Section Material: Nitinol Coil Material Distal to Distal Shaped Section : Platinum/Tungsten Shaped Section Radiopaque Wire: Platinum/Tungsten Coil Material Proximal to Shaped Section: 304 Stainless Steel Solder: Gold/Tin Hydrophilic Coating: Sodium hyaluronate mixture	10% Iridium Push-wire shrink Tubing: PTFE Introducer Sheath: PTFE/Grilamid	designed to be used in the neurovasculature, and contain radiopaque materials for visualization.
Sterilization and Packaging			
Packaging Materials	Polyethylene Hoop, polycarbonate mounting card, Tyvek/Film Pouch, HDPE Tubing Clips, Chipboard carton	Stored within dispenser coil, Tyvek pouch, and shipping carton.	Packaging materials are similar and typical for medical devices. Both packaging configurations maintain a sterility of the device through the shelf life.
Sterilization Method	Ethylene Oxide	Same	N/A
How Supplied	Sterile, Single Use	Same	N/A

Sterilization and Shelf Life:
The Solitaire™ 2 Revascularization Device is sterilized using a validated, Ethylene Oxide (EO) sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1:2007, *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*. There have been no changes to device sterilization in support of this submission. Therefore, no additional sterilization validation testing is required.

Aging studies for the Solitaire™ 2 Revascularization Device have established the Solitaire™ 2 Revascularization Device packaging remains functional and maintains sterility for up to two years. Aging studies for packaging integrity, seal strength and device functionality were performed and met all acceptance criteria. There have been no changes to the materials of construction, design, manufacturing process, packaging, or sterile load configurations in support of this submission. Therefore, no additional shelf life validation testing is required.

Biocompatibility:
Biocompatibility data for the Solitaire device family was tested for the reference Solitaire™ FR Revascularization Device. The biocompatibility data for the Solitaire™ FR was adopted for the Solitaire™ 2 Revascularization Device. The Solitaire™ Revascularization Device is biocompatible and has been tested in accordance with AAMI/ANSI/ISO 10993-1: 2009, *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*. There have been no changes to the finished device or the manufacturing processes in support of this submission. Therefore, no additional biocompatibility is required. Biocompatibility testing completed for the reference Solitaire™ FR Revascularization Device includes:

Test Category	Test Description	Method	Acceptance Criteria	Conclusion
Cytotoxicity	L929 MTT Cytotoxicity	ISO 10993-5	Viability is ≥70%.	Acceptance criteria met
Sensitization	Guinea Pig Maximization Sensitization	ISO 10993-10	Test article does not elicit a sensitization response.	Acceptance criteria met
Irritation	Intracutaneous Irritation Test	ISO 10993-10	Differences in the mean test and control scores of the extract dermal observations are < 1.0.	Acceptance criteria met
Acute Systemic Toxicity	Acute Systemic Injection Test	ISO 10993-11	No abnormal clinical signs and weight loss in excess of 10%.	Acceptance criteria met
	Materials Mediated Rabbit Pyrogen		Temperature rise ≥0.5ºC	

Test Category	Test Description	Method	Acceptance Criteria	Conclusion
Hemo-compatibility	Hemolysis	ISO 10993-4	No significant differences between the test article extract and negative control article results. The test article is considered non-hemolytic	Acceptance criteria met
	Partial Thromboplastin Time		Clotting times are similar to the negative control and the reference material (HDPE) indicating the device materials are not an activator of the intrinsic coagulation pathway.	
	Platelet and Leukocyte Count		Test article does not adversely affect the platelet and leukocyte components of the blood compared to the reference material.	
	Complement Activation C3a and SC5b-9 Assay		Levels of C3a and SC5b-9 are comparable and less than the positive control.	
	Thrombosis		Thrombo-resistance properties are acceptable in clinical use.	
Genotoxicity	Bacterial Mutagenicity Test	ISO 10993-3	Test article is considered non-mutagenic	Acceptance criteria met
	In-vitro Mouse Lymphoma Assay		Test article is considered non-mutagenic	
	In-vivo Mouse Micronucleus Assay		Test article is considered non-mutagenic	

Performance Data – Bench:
Performance testing conducted to support this Solitaire™ 2 Revascularization Device submission includes particulate testing under simulated use conditions. Performance Bench testing completed for this submission and previously conducted for the reference device, the currently cleared Solitaire™ 2 Revascularization device, includes:

Test Description	Method	Acceptance Criteria	Conclusion
Delivery Force	Peak delivery force was measured through a representative tortuous anatomical model.	Stent must be below delivery force specification.	Acceptance criteria met
Re-sheathing Force	Retrieval force was measured through a representative tortuous anatomical model.	Stent must be below re-sheathing force specification.	Acceptance criteria met
Total System Length	Total system length was measured from the proximal tip of the push-wire to the distal-most tip of the finger marker coils.	System length must meet product specification.	Acceptance criteria met
Fluorosafe Marker Length	The total length of the fluorosafe marker was measured.	Fluorosafe marker length must meet product specification.	Acceptance criteria met
Multiple Re-sheathing Durability	Samples were evaluated on their ability to withstand delivery and withdrawal forces in a representative tortuous model beyond the recommended number of passes and re-sheathings allowed per the Instructions for Use (IFU).	Device must reliably deploy and resheath up to four times.	Acceptance criteria met
Body Marker Tensile	Body Marker tensile strength testing is performed to verify the strength of the laser weld of the Platinum/Iridium markercoil to the Nitinol distal finger of the device.	Body marker should be greater than or equal to existing tensile strength specification.	Acceptance criteria met
Body Marker Radiopacity	Verification analysis of body markers.	The radiopaque body markers must be visible using standard catheter laboratory equipment	Acceptance criteria met

Test Description	Method	Acceptance Criteria	Conclusion
Proximal Marker to Distal Marker	The length of the laser cut and electro-polished stents are measured 100% in process.	Length of stent must meet all inspection criteria	Acceptance criteria met
Torque Response	Samples were evaluated to determine the number of turns required to produce 1 rotation of the distal tip of the device.	Device turns must be less than or equal to torque response criteria	Acceptance criteria met
Torque Strength	Samples were evaluated to determine the number of turns required to break the device in a representative tortuous model.	Device turns must be greater than torque strength criteria	Acceptance criteria met
System Tensile	Samples were evaluated to determine the tensile strength of the full system.	Devices must be greater than or equal to the system tensile criteria	Acceptance criteria met
A_f Temperature	In-process 100% tracking of heat set parameters used to set final A_f	Temperature should be less than or equal to existing A_f temperature specification.	Acceptance criteria met
Radial Force	The radial force was measured 100% in-process.	Stent must be within existing radial force specification.	Acceptance criteria met
Kink Resistance	Kink resistance testing verified the device flexibility across various levels of tortuosity.	Device must be able to maintain vessel wall apposition at a minimum radius bend.	Acceptance criteria met
Clot Removal in a Simulated Neurovascular Model	Both hard and soft clot retrieval success was evaluated in an in vitro tortuous anatomical model.	Overall success rate of the device (usability and effectiveness) must be equal to or better than the predicate* device.	Acceptance criteria met

Test Description	Method	Acceptance Criteria	Conclusion
Particulate Under Simulated Use Conditions	Device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model per USP<788>	Device was evaluated for particulate generation under simulated use in a representative tortuous anatomical model per USP<788>	Acceptance criteria met

*Predicate for K113455, Merci® Retrievers

Performance Data – Animal:

No additional animal performance testing was conducted to support this Solitaire™ 2 Revascularization Device submission. Performance Animal testing previously conducted to support clearance of the reference device, the Solitaire™ 2 Revascularization device, includes:

- An acute and 30 day animal study was performed that assessed safety effectiveness, and usability of the Solitaire™ 2 device as compared to the predicate* device. Safety was evaluated for tissue damage, hemorrhage, and thrombi using angiographic images and histopathological evaluation.
- Histological findings of the Solitaire™ 2 device and the predicate* device for the acute and chronic study demonstrated that the vessel response to neurothrombectomy was comparable between the two devices with no histological remarkable difference in the vessel in regards to tissue injury, hemorrhagic evaluation and thrombogenic evaluation.
- Usability for the acute and chronic study were assessed by an interventionalist on the following attributes after each pass: delivery through catheter, ability to position stent retriever at intended target zone, ability to deploy retriever, ability to re-sheath and reposition, ability to retrieve the device through a guide catheter and device condition. The safety and usability results from the acute and 30-day animal studies suggest that the Solitaire™ 2 device is safe, usable and is equivalent to the predicate* device.

*Predicate for K113455, Merci® Retrievers

Performance Testing – Clinical:

Study Design

SWIFT PRIME (Solitaire™ FR or Solitaire™ 2 With the Intention For Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke) is a global, multicenter, two-arm, prospective, randomized, open, blinded endpoint (PROBE) clinical Investigation Device Exemption (IDE) study comparing neurological disability outcomes (defined by mRS) in Acute Ischemic Stroke (AIS) patients who are treated with either IV t-PA alone or IV t-PA in combination with Solitaire™ FR or Solitaire™ 2 mechanical thrombectomy intervention. Subjects receiving IV t-PA within 4.5 hours of symptom onset were randomized 1:1 to mechanical thrombectomy with Solitaire within 6 hours of onset, or to continuation with IV t-PA alone. Within this group, the Analysis cohort was

defined as those subjects who were administered IV t-PA within 3 hours of symptom onset.

Sample Size

A total of 196 subjects were randomized into the SWIFT PRIME Study (98 in each group). The SWIFT PRIME study allowed IV t-PA use beyond 3 hours, although IV t-PA is not approved in the United States beyond 3 hours. Patients treated with IV t-PA beyond 3 hours did not factor strongly in the evaluation of the Solitaire 2 revascularization device and have been excluded from the analyses. The resulting Analysis Cohort consists of 161 subjects (84 in the IV t-PA plus Solitaire™ group and 77 with IV t-PA only). Additionally, 17 subjects in the IV t-PA plus Solitaire™ group were excluded from the primary and secondary efficacy endpoint analyses. These 17 subjects either received carotid stenting and/or angioplasty or were treated in a manner inconsistent with the Solitaire Instructions for Use. Therefore, the primary and secondary efficacy endpoint analyses cohort consists of 144 subjects.

Statistical Analysis

Standard summary statistics were calculated for all study variables and subject data were analyzed according to the group to which they were randomized. For continuous variables, statistics included means, standard deviations, medians and ranges. Categorical variables were summarized in frequency distributions.

For the primary efficacy endpoint, statistical significance was declared using bounds predefined in the group sequential analysis plan, which accounts for multiplicity due to interim analyses. Elsewhere, one-sided statistical tests having p-values less than 0.025 were deemed significant while two-sided tests having p-values less than 0.05 were deemed significant.

For adverse event reporting, the primary analysis is based on subject counts, not event counts. Both subject counts and event counts are presented in tabular summaries of results.

Study Endpoints

The primary effectiveness endpoint of the study is 90-day global disability assessed via the blinded evaluation of modified Rankin Scale (mRS). Secondary clinical efficacy endpoints of the study are:

- Death due to any cause at 90 days.
- Functional independence as defined by mRS score ≤ 2 at 90 days.
- Change in NIHSS score at 27 ± 6 hours post randomization.

The secondary technical efficacy endpoints of the study are:

- Volume of cerebral infarction as measured by a CT or MRI scan at 27 ± 6 hours post randomization.
- Reperfusion measured by reperfusion ratio on CT or MRI scan 27 ± 6 hours post randomization
- Arterial revascularization measured by TICI 2b or 3 following device use.

- Correlation of RAPID-assessed core infarct volume with 27 ± 6 hours post randomization stroke infarction in subjects who achieved TICI 2b-3 reperfusion without intracranial hemorrhage.

Inclusion Criteria

- Subject or subject's legally authorized representative has signed and dated an Informed Consent Form
- Age 18 – 80
- Clinical signs consistent with acute ischemic stroke
- Pre-stroke Modified Rankin Score less than or equal to 1
- National Institute of Health Stoke Scale (NIHSS) score of at least 8 and less than 30 at the time of randomization
- Initiation of IV t-PA within 4.5 hours of onset of stroke symptoms
- Thrombolysis in Cerebral Infarction (TICI) 0 to 1 flow in the intracranial internal carotid artery, M1 segment of the MCA, or carotid terminus confirmed by CT or MR angiography that is accessible to the Solitaire™ FR or Solitaire™ 2 device
- Subject is able to be treated within 6 hours of stroke symptoms onset and within 1.5 hours from CTA or MRA to groin puncture
- Subject is willing to conduct follow-up visits

Exclusion Criteria

- Subject who is contraindicated to IV t-PA as per local national guidelines
- Females who are pregnant or lactating
- Rapid neurological improvement prior to randomization suggesting resolution of signs/symptoms of stroke
- Known serious sensitivity to radiographic contrast agents
- Known sensitivity to Nickel, Titanium metals or their alloys
- Current participation in another investigational drug or device study
- Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency
- Renal failure as defined by a serum creatinine greater than 2.0 mg/dl (or 176.8 µmol/l) or Glomerular Filtration Rate [GFR] less than 30
- Requires hemodialysis or peritoneal dialysis, or who have contraindication to an angiogram
- Life expectancy less than 90 days
- Clinical presentation suggests a subarachnoid hemorrhage, even if initial CT or MRI scan is normal
- Suspicion of aortic dissection
- Co-morbid disease or condition that would confound the neurological and functional evaluations or compromise survival or ability to complete follow-up assessments
- Currently uses or has a recent history of illicit drug(s) or abuses alcohol
- Known history of arterial tortuosity, pre-existing stent, and/or other arterial disease which would prevent the device from reaching the target vessel and/or preclude safe recovery of the device

- Additionally, subjects were also considered ineligible for study participation if they met any of the following imaging exclusion criteria:
  - CT or MRI evidence of hemorrhage on presentation, mass effect or intracranial tumor (except small meningioma), cerebral vasculitis, basilar artery (BA) occlusion or posterior cerebral artery (PCA) occlusion, carotid dissection, or complete cervical carotid occlusion requiring stenting at the time of the index procedure
  - CT showing hypodensity or MRI showing hyperintensity involving greater than 1/3 of the middle cerebral artery (MCA) territory (or in other territories, >100 cc of tissue) on presentation
  - Baseline non-contrast CT or DWI MRI evidence of a moderate/large core defined as extensive early ischemic changes of Alberta Stroke Program Early CT score (ASPECTS) less than 6. Patients enrolled under RAPID were excluded based on the following:
    a) MRI- or CT-assessed core infarct lesion greater than 50 cc; or
    b) Severe hypoperfusion lesion (10 sec or more Tmax lesion larger than 100 cc; or
    c) Ischemic penumbra < 15 cc and mismatch ratio ≤1.8.
  - Evidence that suggests, in the opinion of the investigator, the subject is not appropriate for mechanical thrombectomy intervention

Reason for Screen Failure

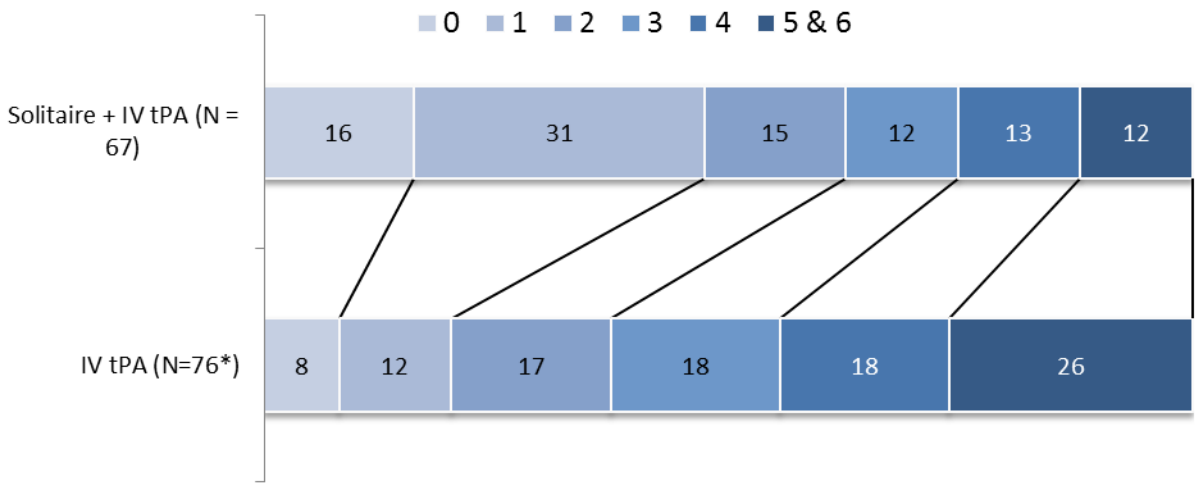
Table 12. Screen Failure	
Reason for Screen Failure	**Subjects (no.)**
Thrombolysis in Cerebral Infarction (TICI) > 1 flow in the intracranial internal carotid artery, M1 segment of the MCA, or carotid terminus confirmed by CT or MR angiography that is accessible to the Solitaire™ FR Device.	28
MRI- or CT-assessed core infarct lesion greater than 50 cc; severe hypoperfusion lesion (Tmax>10secs lesion greater than 100 cc); and/or Ischemic penumbra < 15 cc and mismatch ratio ≤1.8.	17
CT showing hypodensity or MRI showing hyperintensity involving greater than 1/3 of the middle cerebral artery (MCA) territory (or in other territories, >100 cc of tissue) on presentation.	6
NIHSS < 8 or ≥ 30 at the time of randomization	9
CTA or MRA evidence of carotid dissection or complete cervical carotid occlusion.	3
CT or MRI evidence of mass effect or intra-cranial tumor (except small meningioma).	3
Rapid neurological improvement prior to study randomization suggesting resolution of signs/symptoms of stroke.	4
Pre-stroke Modified Rankin Score> 1	2
Baseline non-contrast CT or DWI MRI evidence of a moderate/large core defined as extensive early ischemic changes of Alberta Stroke Program Early CT score (ASPECTS) < 6.	3
Imaging evidence that suggests, in the opinion of the investigator, the subject is not appropriate for mechanical thrombectomy intervention (e.g., inability to navigate to target lesion, moderate/large infarct with poor collateral circulation, etc.).	3
Previous intracranial hemorrhage, neoplasm, subarachnoid hemorrhage, cerebral aneurysm, or	2

Table 12. Screen Failure	
Reason for Screen Failure	**Subjects (no.)**
arteriovenous malformation.	
CTA or MRA evidence of carotid dissection or complete cervical carotid occlusion requiring stenting at the time of the index procedure (i.e., mechanical thrombectomy).	3
Subject is unwilling to conduct protocol-required follow-up visits.	1
Age >80 years old	1
Known hereditary or acquired hemorrhagic diathesis, coagulation factor deficiency.	1
Contraindication to IV t-PA as per local national guidelines.	1
History of stroke in the past 3 months.	1
Arterial tortuosity, calcification, pre-existing stent, and/or stenosis which would prevent the device from reaching the target vessel and/or preclude safe recovery of the device.	2
Subject is unable to be treated within 6 hours of onset of stroke symptoms and within 1.5 hours (90 minutes) from qualifying imaging to groin puncture.	2
CT or MRI evidence of a basilar artery (BA) occlusion or posterior cerebral artery (PCA) occlusion.	1
No certified rater available to assess ASPECTS prior to study enrollment	1
Total	**77***
* Column does not sum to 77 due to some subjects having more than 1 screen failure reason	

Primary Safety and Efficacy Outcomes

The proportion of patients functionally independent (mRS 0-2) at the 90-day visit was higher in the IV t-PA plus Solitaire™ device group.

Primary Effectiveness Endpoint (Analysis Cohort)			
mRS Score at 90 days	**IV t-PA Only***	**IV t-PA + Solitaire**	**p-value**
			0.0007
0	7.9% (6/76)	16.4% (11/67)	
1	11.8% (9/76)	31.3% (21/67)	
2	17.1% (13/76)	14.9% (10/67)	
3	18.4% (14/76)	11.9% (8/67)	
4	18.4% (14/76)	13.4% (9/67)	
5/6	26.3% (20/76)	11.9% (8/67)	
Missing data at 90-day was imputed using LOCF (except baseline data not used) *One subject from the IV t-PA only group withdrew consent 27 hours post randomization. No 90 day mRS Score was available for this subject.			



*One subject from the IV t-PA only group withdrew consent 27 hours post randomization. No 90 day mRS Score was available for this subject.

Modified Rankin Shift at 90 days (Analysis Cohort)

Primary Safety Endpoints (Analysis Cohort)			
Safety Endpoint	**IV t-PA Only**	**IV t-PA + Solitaire**	**Odds Ratio**
Primary Safety Variables			
Any serious adverse event*	33.8% (26/77)	31.0% (26/84)	0.88 (0.45-1.70)
Symptomatic ICH at 27 hours**	3.9% (3/77)	0.0% (0/84)	NA
NA denotes not applicable *Per Clinical Events Committee adjudication **Per Core Laboratory assessed data			

Safety Endpoints, RAPID Imaging Requirement Subgroup (Analysis Cohort)			
Safety Endpoint	**IV t-PA Only**	**IV t-PA + Solitaire**	**Odds Ratio**
All Serious Adverse Events*	43.3% (13/30)	42.9% (12/28)	0.98 (0.35-2.77)
Symptomatic ICH at 27 hours**	0.0% (0/30)	0.0% (0/28)	NA
NA denotes not applicable *Per Clinical Events Committee adjudication **Per Core Laboratory assessed data Patients enrolled under RAPID were excluded based on the following: a) MRI- or CT-assessed core infarct lesion greater than 50 cc; or b) Severe hypoperfusion lesion (10 sec or more Tmax lesion larger than 100 cc; or c) Ischemic penumbra < 15 cc and mismatch ratio ≤1.8.			

Safety Endpoints, ASPECTS Imaging Requirement Subgroup (Analysis Cohort)			
Safety Endpoint	**IV t-PA Only**	**IV t-PA + Solitaire**	**Odds Ratio**
All Serious Adverse Events*	29.8% (14/47)	25.0% (14/56)	0.79 (0.33-1.88)
Symptomatic ICH at 27 hours**	6.4% (3/47)	0.0% (0/56)	NA
NA denotes not applicable *Per Clinical Events Committee adjudication **Per Core Laboratory assessed data Subjects enrolled under ASPECTS were excluded based on ASPECTS score <6.			

Key Secondary Outcomes

Secondary Clinical Efficacy Endpoints (Analysis Cohort)				
Secondary Clinical Efficacy Endpoint	**IV t-PA Only***	**IV t-PA + Solitaire**	**Odds Ratio/ Difference [95% CI]**	**p-value**
Mortality at 90 days	10/76 (13.2%)	6/67 (9.0%)	0.65 (0.22-1.89)	0.596
Functional Independence (mRS 0-2) at 90 days	28/76 (36.8%)	42/67 (62.7%)	2.88 (1.46-5.68)	0.003**
Change in NIHSS at 27 hours Post randomization				
N	76	66		<0.001**
Mean ± SD	-4.3 ± 6.4	-9.9 ± 7.2	-5.6 (-7.9, -3.3)	
Median	-3.0	-9.5		
(min, max)	(-24, 9)	(-27.0,10.0)		
*One subject from the IV t-PA only group withdrew consent 27 hours post randomization. No secondary clinical efficacy endpoints were available for this subject. **These p-values are for informative purposes only. Based on the pre-defined hierarchical testing of the secondary endpoints, these particular endpoints were not achieved.				

Secondary Technical Efficacy Endpoints (Analysis Cohort)			
Secondary Technical Efficacy Endpoint	**IV t-PA Only**	**IV t-PA + Solitaire**	**Difference [95% CI]**
Infarct Volume at 27 hours Post-Randomization (cc)**			
N	77	66	
Mean ± SD	68.9 ± 75.5	51.1 ± 86.1	N/A*
Median	46.5	19.2	
(min, max)	(0.0, 406.6)	(0.0,530.5)	
Reperfusion Ratio at 27 hours Post-Randomization**			
N	44	45	
Mean ± SD	61.6 ± 56.1	87.9 ± 37.2	N/A*
Median	84.0	100.0	
(min, max)	(-200, 100)	(-94.0,100.0)	
TICI 2b-3 Following Device Use**			
% (n/N)	N/A	90.2% (55/61)	N/A
*Wilcoxon rank-sum test due to non-normality of data. ** Per Core Laboratory assessed data			

Important Safety Results

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
TOTAL Adverse Events (AE)	**93.5% (72/77) [416]**	**91.7% (77/84) [449]**	**92.5% (149/161) [865]**
Blood and Lymphatic System Disorders	**6.5% (5/77) [5]**	**13.1% (11/84) [11]**	**9.9% (16/161) [16]**
Anaemia	3.9% (3/77) [3]	6.0% (5/84) [5]	5.0% (8/161) [8]
Haemorrhagic Anaemia	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Leukocytosis	1.3% (1/77) [1]	7.1% (6/84) [6]	4.3% (7/161) [7]
Cardiac Disorders	**26.0% (20/77) [23]**	**31.0% (26/84) [31]**	**28.6% (46/161) [54]**
Atrial Fibrillation	3.9% (3/77) [3]	6.0% (5/84) [5]	5.0% (8/161) [8]
Atrial Flutter	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Atrial Thrombosis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Bradycardia	7.8% (6/77) [6]	4.8% (4/84) [4]	6.2% (10/161) [10]
Cardiac Arrest	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Cardiac Failure	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Cardiac Failure Congestive	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Intracardiac thrombus	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Ischaemic cardiomyopathy	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Myocardial infarction	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Palpitations	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Sick sinus syndrome	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Sinus arrest	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Supraventricular tachycardia	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Tachycardia	11.7% (9/77) [9]	8.3% (7/84) [7]	9.9% (16/161) [16]
Ventricular tachycardia	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Ear and Labyrinth Disorders	**1.3% (1/77) [1]**	**0.0% (0/84) [0]**	**0.6% (1/161) [1]**
Vertigo	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Endocrine disorders	**0.0% (0/77) [0]**	**1.2% (1/84) [1]**	**0.6% (1/161) [1]**
Hypothyroidism	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Eye disorders	**1.3% (1/77) [1]**	**4.8% (4/84) [4]**	**3.1% (5/161) [5]**
Conjunctival haemorrhage	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Eye haemorrhage	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Optic neuropathy	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Photopsia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Visual impairment	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Gastrointestinal Disorders	**37.7% (29/77) [40]**	**33.3% (28/84) [43]**	**35.4% (57/161) [83]**
Abdominal pain	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Abdominal pain lower	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Abdominal pain upper	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Constipation	15.6% (12/77) [13]	15.5% (13/84) [13]	15.5% (25/161) [26]
Diarrhea	3.9% (3/77) [3]	1.2% (1/84) [1]	2.5% (4/161) [4]
Dyspepsia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Dysphagia	9.1% (7/77) [7]	7.1% (6/84) [6]	8.1% (13/161) [13]
Faecal incontinence	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Gastritis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Gastrooesophageal reflux disease	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Haematemesis	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Haemorrhoidal haemorrhage	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Ileus	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Intestinal ischaemia	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Lower gastrointestinal haemorrhage	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Melaena	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Mouth haemorrhage	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Nausea	5.2% (4/77) [4]	8.3% (7/84) [7]	6.8% (11/161) [11]
Oesophageal stenosis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Oral pain	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Retroperitoneal haematoma	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Salivary hypersecretion	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Vomiting	3.9% (3/77) [3]	4.8% (4/84) [4]	4.3% (7/161) [7]
General Disorders and Administration Site Conditions	**18.2% (14/77) [16]**	**25.0% (21/84) [24]**	**21.7% (35/161) [40]**
Application site pruritus	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Catheter site haematoma	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Catheter site haemorrhage	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Catheter site induration	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Catheter site inflammation	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Cyst	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Discomfort	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Extravasation	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Fatigue	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Influenza like illness	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Local swelling	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Oedema peripheral	5.2% (4/77) [4]	0.0% (0/84) [0]	2.5% (4/161) [4]
Pain	2.6% (2/77) [2]	4.8% (4/84) [4]	3.7% (6/161) [6]
Pyrexia	6.5% (5/77) [5]	8.3% (7/84) [7]	7.5% (12/161) [12]
Systemic inflammatory response syndrome	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Temperature intolerance	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Hepatobiliary Disorders	**2.6% (2/77) [2]**	**0.0% (0/84) [0]**	**1.2% (2/161) [2]**
Cholecystitis acute	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Cholestasis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Immune System Disorders	**2.6% (2/77) [2]**	**2.4% (2/84) [2]**	**2.5% (4/161) [4]**
Drug hypersensitivity	1.3% (1/77) [1]	2.4% (2/84) [2]	1.9% (3/161) [3]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Immune system disorder	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Infections and Infestations	**45.5% (35/77) [53]**	**38.1% (32/84) [42]**	**41.6% (67/161) [95]**
Acute sinusitis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Bacterial disease carrier	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Bronchitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Candida infection	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Cellulitis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Clostridium colitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Conjunctivitis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Cystitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Endocarditis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Fungal infection	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Fungal skin infection	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Gastroenteritis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Genital infection fungal	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Hand-foot-and-mouth disease	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Herpes zoster	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Oral candidiasis	3.9% (3/77) [3]	2.4% (2/84) [2]	3.1% (5/161) [5]
Parotitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Pneumonia	7.8% (6/77) [6]	9.5% (8/84) [8]	8.7% (14/161) [14]
Respiratory syncytial virus infection	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Respiratory tract infection	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Rhinitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Sepsis	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Septic shock	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Sinusitis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Skin candida	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Urinary tract infection	31.2% (24/77) [28]	20.2% (17/84) [19]	25.5% (41/161) [47]
Wound infection	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Injury, Poisoning and Procedural Complications	**10.4% (8/77) [8]**	**10.7% (9/84) [11]**	**10.6% (17/161) [19]**
Ankle fracture	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Carotid artery restenosis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Fall	3.9% (3/77) [3]	3.6% (3/84) [4]	3.7% (6/161) [7]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Joint dislocation	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Post procedural haematoma	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Procedural pain	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Procedural vomiting	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Pseudomeningocele	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Subdural haematoma	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Tracheal injury	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Vascular pseudoaneurysm	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Investigations	**14.3% (11/77) [12]**	**17.9% (15/84) [19]**	**16.1% (26/161) [31]**
Biopsy salivary gland	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Blood creatine phosphokinase increased	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Blood creatinine increased	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Blood glucose increased	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Blood magnesium abnormal	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Blood pressure increased	7.8% (6/77) [6]	9.5% (8/84) [9]	8.7% (14/161) [15]
Blood urea increased	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Electrocardiogram ST segment depression	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Glycosylated haemoglobin increased	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Transaminases increased	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Troponin increased	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Urine output decreased	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Metabolism and Nutrition Disorders	**40.3% (31/77) [40]**	**33.3% (28/84) [42]**	**36.6% (59/161) [82]**
Decreased appetite	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Dehydration	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Diabetes mellitus	3.9% (3/77) [3]	0.0% (0/84) [0]	1.9% (3/161) [3]
Dyslipidaemia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Electrolyte imbalance	7.8% (6/77) [6]	4.8% (4/84) [4]	6.2% (10/161) [10]
Fluid retention	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Glucose tolerance impaired	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Gout	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Hypercholesterolaemia	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Hyperglycaemia	5.2% (4/77) [4]	4.8% (4/84) [4]	5.0% (8/161) [8]
Hyperlipidaemia	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Hypernatraemia	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Hypervolaemia	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Hypocalcaemia	2.6% (2/77) [2]	3.6% (3/84) [3]	3.1% (5/161) [5]
Hypokalaemia	5.2% (4/77) [4]	15.5% (13/84) [13]	10.6% (17/161) [17]
Hypomagnesaemia	5.2% (4/77) [4]	6.0% (5/84) [5]	5.6% (9/161) [9]
Hyponatraemia	2.6% (2/77) [2]	3.6% (3/84) [3]	3.1% (5/161) [5]
Hypophosphataemia	3.9% (3/77) [3]	1.2% (1/84) [1]	2.5% (4/161) [4]
Hypoproteinaemia	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Vitamin D deficiency	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Musculoskeletal and Connective Tissue Disorders	**20.8% (16/77) [20]**	**15.5% (13/84) [15]**	**18.0% (29/161) [35]**
Arthralgia	6.5% (5/77) [6]	3.6% (3/84) [4]	5.0% (8/161) [10]
Back pain	3.9% (3/77) [3]	3.6% (3/84) [3]	3.7% (6/161) [6]
Groin pain	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Joint swelling	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Muscle spasms	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Musculoskeletal chest pain	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Musculoskeletal pain	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Neck pain	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Osteoarthritis	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Pain in extremity	5.2% (4/77) [4]	3.6% (3/84) [3]	4.3% (7/161) [7]
Neoplasms Benign, Malignant and Unspecified (incl cysts and polyps)	**1.3% (1/77) [2]**	**0.0% (0/84) [0]**	**0.6% (1/161) [2]**
Appendix cancer	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Haemangioma of liver	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Nervous System Disorders	**66.2% (51/77) [90]**	**51.2% (43/84) [83]**	**58.4% (94/161) [173]**
Brain oedema	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Carotid artery dissection	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Carotid artery thrombosis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Cerebral artery embolism	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Cerebral haemorrhage	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Cerebral vasoconstriction	0.0% (0/77) [0]	13.1% (11/84) [11]	6.8% (11/161) [11]
Complex regional pain syndrome	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Convulsion	6.5% (5/77) [5]	1.2% (1/84) [1]	3.7% (6/161) [6]
Dizziness	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Encephalopathy	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Haemorrhagic transformation stroke	39.0% (30/77) [31]	29.8% (25/84) [26]	34.2% (55/161) [57]
Headache	15.6% (12/77) [12]	16.7% (14/84) [15]	16.1% (26/161) [27]
Hemianopia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Horner's syndrome	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Hydrocephalus	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Hypertonia	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Intracranial pressure increased	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Intraventricular haemorrhage	3.9% (3/77) [3]	4.8% (4/84) [4]	4.3% (7/161) [7]
Ischaemic stroke	9.1% (7/77) [7]	3.6% (3/84) [4]	6.2% (10/161) [11]
Lethargy	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Migraine	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Monoparesis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Muscle spasticity	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Neuralgia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Paraesthesia	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Partial seizures	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Somnolence	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Status epilepticus	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Stroke in evolution	10.4% (8/77) [8]	6.0% (5/84) [5]	8.1% (13/161) [13]
Subarachnoid haemorrhage	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Syncope	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Transient ischaemic attack	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Tremor	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Psychiatric Disorders	**32.5% (25/77) [29]**	**33.3% (28/84) [35]**	**32.9% (53/161) [64]**
Acute psychosis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Agitation	10.4% (8/77) [8]	7.1% (6/84) [6]	8.7% (14/161) [14]
Alcohol withdrawal syndrome	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Anxiety	3.9% (3/77) [3]	2.4% (2/84) [3]	3.1% (5/161) [6]
Confusional state	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Depressed mood	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Depression	14.3% (11/77) [11]	15.5% (13/84) [13]	14.9% (24/161) [24]
Depressive symptom	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Insomnia	5.2% (4/77) [4]	8.3% (7/84) [7]	6.8% (11/161) [11]
Mental status changes	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Restlessness	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Sleep disorder	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Stress	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Renal and Urinary Disorders	**19.5% (15/77) [16]**	**16.7% (14/84) [16]**	**18.0% (29/161) [32]**
Dysuria	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Haematuria	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Hypertonic bladder	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Oliguria	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Polyuria	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Renal failure	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Renal failure acute	3.9% (3/77) [3]	4.8% (4/84) [4]	4.3% (7/161) [7]
Renal infarct	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Renal mass	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Urethral pain	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Urge incontinence	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Urinary retention	3.9% (3/77) [3]	8.3% (7/84) [7]	6.2% (10/161) [10]
Reproductive System and Breast Disorders	**0.0% (0/77) [0]**	**2.4% (2/84) [2]**	**1.2% (2/161) [2]**
Benign prostatic hyperplasia	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Respiratory, Thoracic and Mediastinal Disorders	**29.9% (23/77) [27]**	**26.2% (22/84) [32]**	**28.0% (45/161) [59]**
Acute respiratory failure	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Aspiration	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Atelectasis	2.6% (2/77) [2]	3.6% (3/84) [3]	3.1% (5/161) [5]
Chronic obstructive pulmonary disease	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Cough	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Dyspnoea	1.3% (1/77) [1]	2.4% (2/84) [2]	1.9% (3/161) [3]
Haemoptysis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Hiccups	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Hypoxia	1.3% (1/77) [1]	2.4% (2/84) [2]	1.9% (3/161) [3]
Oropharyngeal pain	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Pleural effusion	1.3% (1/77) [1]	4.8% (4/84) [4]	3.1% (5/161) [5]

CEC Adjudicated Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
Pneumonia aspiration	6.5% (5/77) [5]	7.1% (6/84) [6]	6.8% (11/161) [11]
Pulmonary congestion	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Pulmonary embolism	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Pulmonary oedema	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Respiratory arrest	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Respiratory distress	5.2% (4/77) [4]	1.2% (1/84) [1]	3.1% (5/161) [5]
Respiratory failure	2.6% (2/77) [2]	3.6% (3/84) [3]	3.1% (5/161) [5]
Sleep apnoea syndrome	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Wheezing	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Skin and Subcutaneous Tissue Disorders	**13.0% (10/77) [10]**	**11.9% (10/84) [10]**	**12.4% (20/161) [20]**
Decubitus ulcer	0.0% (0/77) [0]	4.8% (4/84) [4]	2.5% (4/161) [4]
Dermatitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Dermatitis contact	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Ecchymosis	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Erythema	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]
Intertrigo	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Pruritus	1.3% (1/77) [1]	1.2% (1/84) [1]	1.2% (2/161) [2]
Rash	1.3% (1/77) [1]	2.4% (2/84) [2]	1.9% (3/161) [3]
Rash erythematous	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Skin lesion	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Surgical and Medical Procedures	**1.3% (1/77) [1]**	**0.0% (0/84) [0]**	**0.6% (1/161) [1]**
Gastrostomy tube removal	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Vascular Disorders	**20.8% (16/77) [18]**	**25.0% (21/84) [26]**	**23.0% (37/161) [44]**
Aortic aneurysm	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Arterial rupture	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Deep vein thrombosis	7.8% (6/77) [6]	6.0% (5/84) [5]	6.8% (11/161) [11]
Femoral artery embolism	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Haematoma	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Hypertension	3.9% (3/77) [3]	6.0% (5/84) [5]	5.0% (8/161) [8]
Hypotension	5.2% (4/77) [4]	6.0% (5/84) [5]	5.6% (9/161) [9]
Lymphoedema	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Phlebitis	1.3% (1/77) [1]	0.0% (0/84) [0]	0.6% (1/161) [1]
Thrombophlebitis	1.3% (1/77) [1]	3.6% (3/84) [3]	2.5% (4/161) [4]
Thrombosis	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Vascular occlusion	0.0% (0/77) [0]	1.2% (1/84) [1]	0.6% (1/161) [1]
Vasospasm	0.0% (0/77) [0]	3.6% (3/84) [3]	1.9% (3/161) [3]

CEC Adjudicated Serious Adverse Events (Analysis Cohort)			
MedDRA Preferred Term	**IV t-PA Only**	**IV t-PA + Solitaire**	**All Enrolled**
Units	% (pts/N) [AEs]	% (pts/N) [AEs]	% (pts/N) [AEs]
TOTAL Adverse Events (AE)	**33.8% (26/77) [54]**	**31.0% (26/84) [44]**	**32.3% (52/161) [98]**
Blood and Lymphatic System Disorders	**0.0% (0/77) [0]**	**2.4% (2/84) [2]**	**1.2% (2/161) [2]**
Anaemia	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Cardiac Disorders	**5.2% (4/77) [5]**	**8.3% (7/84) [8]**	**6.8% (11/161) [13]**
Cardiac Arrest	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Intracardiac thrombus	0.0% (0/77) [0]	2.4% (2/84) [2]	1.2% (2/161) [2]
Tachycardia	2.6% (2/77) [2]	0.0% (0/84) [0]	1.2% (2/161) [2]
Gastrointestinal Disorders	**2.6% (2/77) [2]**	**2.4% (2/84) [2]**	**2.5% (4/161) [4]**
Infections and Infestations	**7.8% (6/77) [7]**	**3.6% (3/84) [3]**	**5.6% (9/161) [10]**
Sepsis	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Injury, Poisoning and Procedural Complications	**3.9% (3/77) [3]**	**3.6% (3/84) [3]**	**3.7% (6/161) [6]**
Nervous System Disorders	**20.8% (16/77) [21]**	**11.9% (10/84) [12]**	**16.1% (26/161) [33]**
Brain oedema	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Haemorrhagic transformation stroke	5.2% (4/77) [4]	0.0% (0/84) [0]	2.5% (4/161) [4]
Ischaemic stroke	6.5% (5/77) [5]	2.4% (2/84) [3]	4.3% (7/161) [8]
Stroke in evolution	10.4% (8/77) [8]	4.8% (4/84) [4]	7.5% (12/161) [12]
Renal and Urinary Disorders	**3.9% (3/77) [3]**	**3.6% (3/84) [3]**	**3.7% (6/161) [6]**
Renal failure acute	1.3% (1/77) [1]	2.4% (2/84) [2]	1.9% (3/161) [3]
Respiratory, Thoracic and Mediastinal Disorders	**9.1% (7/77) [8]**	**7.1% (6/84) [7]**	**8.1% (13/161) [15]**
Respiratory distress	3.9% (3/77) [3]	0.0% (0/84) [0]	1.9% (3/161) [3]
Respiratory failure	2.6% (2/77) [2]	2.4% (2/84) [2]	2.5% (4/161) [4]
Vascular Disorders	**5.2% (4/77) [4]**	**3.6% (3/84) [3]**	**4.3% (7/161) [7]**
Deep vein thrombosis	2.6% (2/77) [2]	1.2% (1/84) [1]	1.9% (3/161) [3]

CEC-Adjudicated Device-Related Adverse Events			
Terminology	**Severity**	**Outcome**	**Neurological deterioration or death**
Subarachnoid Contrast	Mild	Recovered without sequelae	None

CEC-Adjudicated Device-Related Adverse Events			
Terminology	**Severity**	**Outcome**	**Neurological deterioration or death**
Extravasation			
Cerebral Vasospasm	Moderate	Recovered without sequelae	None
Intraventricular Hemorrhage	Mild	Recovered without sequelae	None
Subarachnoid Hemorrhage	Mild	Recovered without sequelae	None
Cerebral Vasospasm	Mild	Recovered without sequelae	None
Cerebral Vasospasm	Moderate	Recovered without sequelae	Brain edema 1 day post-ADE, alive through study follow-up

Conclusion

In the SWIFT PRIME Study (IDE G120142) the proportion of patients functionally independent (mRS 0-2) at the 90-day visit was higher in the IV t-PA plus Solitaire™ device group than the IV t-PA only group (62.7% of patients versus 36.8% of patients, respectively).

The Trevo clinical data includes a clinical trial comparing 96 randomly selected patients treated with the Trevo device with IV t-PA and medical management of blood pressure and disability symptoms to 249 patients who had only t-PA and medical management. In this study, more patients treated with the Trevo device were functionally independent (ranging from no symptoms to slight disability) at three months after their stroke, compared to patients who were not treated with the Trevo device (29% of patients versus 19% of patients, respectively).

Both the SWIFT PRIME clinical study and the Trevo clinical data evaluated functional independence at 3 months using mRS 0-2 as a measurement for success. The data from the SWIFT PRIME Study demonstrates that the Solitaire™ 2 Revascularization device, in combination with IV t-PA, is substantially equivalent to the Trevo XP ProVue Retriever, in combination with IV t-PA, in the treatment of acute ischemic stroke to reduce disability in patients with a persistent proximal anterior circulation large vessel occlusion and smaller core infarcts who have first received intravenous tissue plasminogen activator (IV t-PA).