The study’s primary safety endpoint was Major Adverse Events ("MAE"), which was a composite of:
- Device-related death within 48 hours (± 8 hours) of the procedure
- Major bleeding within 48 hours (± 8 hours) of the procedure
- Clinical deterioration within 48 hours (± 8 hours) of the procedure
- Pulmonary vascular injury within 48 hours (± 8 hours) of the procedure
- Cardiac injury within 48 hours (± 8 hours) of the procedure
- Mortality due to any cause within 30 days (± 3 days) of the procedure
- Device-related serious adverse events within 30 days (± 3 days) of the procedure
- Symptomatic recurrence of embolism within 30 days (± 3 days) of the procedure

Exclusion Criteria:
1) Age ≥ 18 and ≤ 75 years;
2) Clinical signs, symptoms and presentation consistent with acute PE;
3) PE symptom duration ≥ 14 days;
4) CTA evidence of proximal PE;
5) RV/LV ratio of ≥ 0.9;
6) Systolic blood pressure ≥ 90 mmHg;
7) Stable heart rate < 130 BPM prior to procedure;
8) Patient is deemed medically eligible for interventional procedure(s), per institutional guidelines and clinical judgment

Inclusion Criteria:
1) Thrombolytic use within 30 days of baseline CTA;
2) Pulmonary hypertension with peak pulmonary artery pressure > 70 mmHg by right heart catheterization;
3) Vasopressor requirement after fluids to keep pressure ≥ 90 mmHg;
4) FiO2 requirement > 40% or > 6 LPM to keep oxygen saturation > 90%;
5) Hematocrit < 28%;
6) Platelets < 100,000/µL;
7) Serum creatinine > 1.8 mg/dL;
8) International normalized ratio (INR) > 3;
9) Major trauma injury severity score (ISS) > 15;
10) Presence of intracardiac lead in the right ventricle or right atrium placed within 6 months;
11) Cardiovascular or pulmonary surgery within last 7 days;
12) Actively progressing cancer;
13) Known bleeding diathesis or coagulation disorder;
14) Left bundle branch block;
15) History of severe or chronic pulmonary arterial hypertension;
16) History of chronic left heart disease with left ventricular ejection fraction ≤ 30%;
17) History of uncompensated heart failure;
18) History of underlying lung disease that is oxygen dependent;
19) History of chest irradiation;
20) History of heparin-induced thrombocytopenia (HIT);
21) Any contraindication to systemic or therapeutic doses of heparin or anticoagulants;
22) Known anaphylactic reaction to radiographic contrast agents that cannot be pretreated;
23) Imaging evidence or other evidence that suggests, in the opinion of the Investigator, the Subject is not appropriate for mechanical thrombectomy intervention;
24) Life expectancy of < 90 days, as determined by Investigator;
25) Female who is pregnant or nursing;
26) Current participation in another investigational drug or device treatment study

Results
A total of 106 subjects that met the eligibility criteria were consecutively enrolled and treated with the FlowTriever System comprising the full Intent-To-Treat (“ITT”) population. Of these 106 subjects, two (2) subjects received thrombolytics during their index procedure and were therefore not included in the modified Intent-To-Treat (mITT) population. The mITT Population was defined as all subjects in the “ITT Population” with no thrombolytics administered during the operative procedure. The primary effectiveness and safety analyses were done using the mITT population.

1 It should be noted that the FlowTriever Retrieval/Aspiration System has been modified from the version used in this clinical study to allow the removal of the FlowTriever Catheter from the patient without the simultaneous removal of the Trierve20, also allowing the FlowTriever Catheter to make multiple passes while the Trierve20 remains in place. These changes were adequately evaluated with bench data. The clinical data presented here on the previous version of the FlowTriever Retrieval/Aspiration System remains applicable.
2 DISCLAIMER: A single component of the FlowTriever Retrieval/Aspiration System has not been demonstrated to be safe and effective for the treatment of PE.
Assessment of the FlowTriever System Performance and Safety in Acute Symptomatic Pulmonary Embolism

**Primary Endpoint Analysis – mITT**

The lower one-sided 95% confidence limit is 8.6% (which was less than 25%), so we can conclude that the composite MAE rate in the mITT population was 3.8% and the p-value < 0.0001, indicating that the null hypothesis is rejected. Additionally, the upper one-sided 95% confidence limit is 0.32 (which was greater than 0.12), so we can conclude that the mean change in RV/LV ratio was significantly greater than the performance goal and the FlowTriever device met the performance goal at the 0.05 one-sided significance level.

The resulting mean change in RV/LV ratio was 0.37 and the p-value < 0.0001, indicating that the null hypothesis is rejected. Additionally, the median number of passes with a FlowTriever device per procedure was 3.9 (± 1.7) with a range from 1 to 10 passes. The majority of the procedures were completed without technical complications (98.1%, 102/104).

**Primary Safety Analysis**

A total of 106 subjects were treated with the FlowTriever System and comprise the full ITT population. Of these 106 subjects, two (2) subjects received thrombolytics during their index procedure and were not included in the mITT population. All but three (3) subjects completed the study follow-up; one (1) subject died from metastatic breast cancer that was undiagnosed at enrollment, and two (2) subjects were lost to follow-up. Four (4) subjects experienced endpoint-related MAE, all of which were CEC adjudicated to be related MAE, all of which were CEC adjudicated to be.

**Additional Metrics or Variables**

The median length of stay in the ICU following the index procedure was 1 day (mean 1.5 ± 2.1 days) with a range from 0 to 11 days. The median number of days from the index procedure to hospital discharge was 3 days (mean 4.1 ± 3.5 days) with a range from 2 to 25 days.

**Safety**

A total of 106 subjects were treated with the FlowTriever System and comprise the full ITT population. Of these 106 subjects, two (2) subjects received thrombolytics during their index procedure and were not included in the mITT population. All but three (3) subjects completed the study follow-up; one (1) subject died from metastatic breast cancer that was undiagnosed at enrollment, and two (2) subjects were lost to follow-up. Four (4) subjects experienced endpoint-related MAE, all of which were CEC adjudicated to be.

**Secondary Safety Analysis**

In addition to the components of the primary composite endpoint, all-cause mortality, device-related serious AE, serious AE, symptomatic recurrence of embolism, non-serious device related AEs and non-serious procedure-related AEs within 30 days of the procedure were
investigated; rates are presented in Table 1, below.

When the four (4) subjects in the composite MAE were broken down into the individual components, there were six (6) MAE endpoint categories amongst these subjects that comprised the secondary safety endpoint. The major bleeding primary event experienced by one subject was also classified as both pulmonary vascular injury and clinical deterioration. Upon further assessment of the clinical data provided and the CEC adjudication, from surgical pathology the left lower lobectomy clearly demonstrated “diffuse hemorrhage and areas of necrosis consistent with hemorrhagic infarction.” It is important to reiterate that there was no mention of pulmonary artery injury and the pulmonary hemorrhage was consistent with hemorrhagic infarction and was not device related event. The additional secondary safety event belonged to the subject who died from metastatic breast cancer 23 days following the procedure.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Outcome</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite Primary Safety Endpoint</td>
<td></td>
<td>4 (3.8%)</td>
</tr>
<tr>
<td>Secondary Safety Endpoints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device-Related Death Within 48 Hours of Procedure</td>
<td></td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Major Bleeding Within 48 Hours of Procedure</td>
<td></td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>Clinical Deterioration Within 48 Hours of Procedure</td>
<td></td>
<td>4 (3.8%)</td>
</tr>
<tr>
<td>Pulmonary Vascular Injury Within 48 Hours of Procedure</td>
<td></td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>Cardiac Injury Within 48 Hours of Procedure</td>
<td></td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Death Due to Any Cause Within 30 Days of Procedure</td>
<td></td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>Device-Related Serious Adverse Events Within 30 Days of Procedure</td>
<td></td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Symptomatic Recurrence of Embolism Within 30 Days of Procedure</td>
<td></td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Additional Safety Endpoints</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Adverse Events Within 30 Days of Procedure</td>
<td></td>
<td>14 (13.5%)</td>
</tr>
<tr>
<td>Non-Serious Device-Related Adverse Events Within 30 Days of Procedure</td>
<td></td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Non-Serious Procedure-Related Adverse Events Within 30 Days of Procedure</td>
<td></td>
<td>7 (6.7%)</td>
</tr>
</tbody>
</table>

(1) Percentages reflect the number of subjects that experienced each specified outcome at least once.