

**K252057 Symphony™ Thrombectomy System and Symphony™  
16F 82cm Thrombectomy System**Aug 28, 2025  
58 days to decisionK252057 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252057/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                       |
| Submission type       | Traditional  |
| Device classification | Peripheral Mechanical Thrombectomy With Aspiration (QEW) |
| Date received         | Jul 1, 2025  |
| Decision date         | Aug 28, 2025   |
| Days to decision      | 58 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Imperative Care, Inc.</b>            |
| Location       | Sunnyvale, CA, US                       |
| Contact        | Shivani Patel                           |
| 510(k) history | 17 submissions · 17 cleared · 2018-2025 |

**CLINICAL EVIDENCE - NCT06062329****SYMPHONY-PE Study for Treatment of Pulmonary Embolism**

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|                   |  |
|-------------------|--|
| Status            | Completed - <i>No results published to ClinicalTrials.gov</i>  |
| Enrollment        | 109 patients (actual)  |
| Study sites       | 19 sites   |
| Condition studied | Acute Pulmonary Embolism; Thromboembolism; Emboli, Pulmonary; Thrombosis; Thrombus; Embolism; Embolism; Cardiovascular Diseases; Vascular Diseases |
| Primary purpose   | Treatment  |
| Study type        | Interventional   |
| Study design      | Single group   |
| Masking           | Open label   |
| Completion date   | May 29, 2025   |
| Sponsor           | Imperative Care, Inc. (Industry)   |

**Primary outcome**

Rate of major adverse events

**Secondary outcome**

Rates of Major bleeding, device-related mortality, device-related clinical deterioration, device-related pulmonary vascular injury and device-related cardiac injury

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT06062329](https://clinicaltrials.gov/study/NCT06062329)