

K260599 INDIGO® Aspiration System – INDIGO LinkApr 24, 2026
59 days to decisionK260599 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k260599/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Peripheral Mechanical Thrombectomy With Aspiration (QEW) |
| Date received | Feb 24, 2026 |
| Decision date | Apr 24, 2026 |
| Days to decision | 59 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Penumbra, Inc. |
| Location | Alameda, CA, US |
| Contact | Akshay Kulkarni |
| Website | https://www.penumbrainc.com |
| 510(k) history | 86 submissions · 84 cleared · 2005-2026 |

Penumbra, Inc. is a global healthcare company headquartered in Alameda, California. The company focuses on innovative medical devices for neurology and cardiovascular interventions. Penumbra has maintained a strong FDA 510(k) regulatory record since its first clearance in 2005. The company has received FDA 510(k) clearances from total submissions. Recent clearances span neurology devices including thrombectomy and access catheters, as well as cardiovascular aspiration systems and delivery catheters. The company remains actively cleared, with the latest FDA 510(k) clearanc...

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Device record: <https://www.510kdatabase.net/k260599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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