

K214114 Prodigy Thrombectomy SystemApr 6, 2022
97 days to decisionK214114 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k214114/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Peripheral Mechanical Thrombectomy With Aspiration (QEW) |
| Date received | Dec 30, 2021 |
| Decision date | Apr 6, 2022 |
| Days to decision | 97 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Truvic Medical, Inc. |
| Location | Campbell, CA, US |
| Contact | Micheal Buck |
| 510(k) history | 2 submissions · 2 cleared · 2022-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|-------------------------------------|
| Consulting firm | Cardiomed Device Consultants |
| Contact | Semih Oktay |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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