

K203764 TracStar Large Distal Platform, ZOOM 88 Large Distal Platform, ZOOM 88-T Large Distal PlatformMar 3, 2021
70 days to decisionK203764 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k203764/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous, Neurovasculature (QJP) |
| Date received | Dec 23, 2020 |
| Decision date | Mar 3, 2021 |
| Days to decision | 70 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Imperative Care, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Kristin Ellis |
| 510(k) history | 17 submissions · 17 cleared · 2018-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203764/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026