

K223791 TalWireJul 14, 2023
207 days to decisionK223791 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k223791/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Dec 19, 2022 |
| Decision date | Jul 14, 2023 |
| Days to decision | 207 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Embrace Medical , Ltd. |
| Location | Tel-Aviv, IL |
| Contact | Anat Kaufman |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------|
| Consulting firm | Orly Maor |
| Contact | Orly Maor |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223791/> 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 27, 2026