FDA 510(k) Premarket Notification

# K223791 TalWire

**CLEARED**

Jul 14, 2023
207 days to decision

K223791 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k223791/

## SUBMISSION DETAILS

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|---|---|
| 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.gov