FDA 510(k) Premarket Notification

# K254060 Life Saving Tourniquet

**CLEARED**

Apr 3, 2026
107 days to decision

K254060 · Product code: **DXC** · Cardiovascular
Source: https://www.510kdatabase.net/k254060/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Clamp, Vascular (DXC) |
| Date received | Dec 17, 2025 |
| Decision date | Apr 3, 2026 |
| Days to decision | 107 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **TW Medical** |
| Location | Otniel, IL |
| Contact | Yaakov Tsadik |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Rook Quality Systems** |
| Contact | Tyler Ting |

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