

K254060 Life Saving TourniquetApr 3, 2026
107 days to decisionK254060 · Product code: **DXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k254060/>**SUBMISSION DETAILS**

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

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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