

K250779 CS-Pro MEDJul 2, 2025
110 days to decisionK250779 · Product code: **PZL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Mar 14, 2025
Decision date	Jul 2, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Curative Sound Therapeutics
Location	Carmel, IN, US
Contact	Les Bogdanowicz
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250779/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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