FDA 510(k) Premarket Notification

K250779 CS-Pro MED

CLEARED

Jul 2, 2025
110 days to decision

K250779 · Product code: **PZL** · General & Plastic Surgery
Source: 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