

K243279 DOLORCLAST Focused Shock WavesAug 13, 2025
301 days to decisionK243279 · Product code: **PZL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Oct 16, 2024
Decision date	Aug 13, 2025
Days to decision	301 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	E.M.S Electro Medical Systems S.A
Location	North Attleboro, MA, US
Contact	Vivian Yee
510(k) history	28 submissions · 28 cleared · 2005-2026

REGULATORY CONSULTANT

Consulting firm	Heyer Regulatory Solutions
Contact	Sheila Hemeon-Heyer

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

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