FDA 510(k) Premarket Notification

K231710 OW100S

CLEARED

Sep 1, 2023
81 days to decision

K231710 · Product code: **PZL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231710/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Jun 12, 2023
Decision date	Sep 1, 2023
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Softwave/Trt, LLC**
Location	Woodstock, GA, US
Contact	John Warlick
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**M Squared Associates/A Ppg Company**
Contact	Cherita James

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