

**K233937 OW100S**Jul 9, 2024  
208 days to decisionK233937 · Product code: **PZL** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k233937/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Dec 14, 2023
Decision date	Jul 9, 2024
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Softwave/Trt, LLC</b>
Location	Woodstock, GA, US
Contact	Cherita James
510(k) history	2 submissions · 2 cleared · 2023-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233937/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026