

**K200926 OrthoGold 100**Aug 28, 2020  
143 days to decisionK200926 · Product code: **PZL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200926/>**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	Apr 7, 2020
Decision date	Aug 28, 2020
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tissue Regeneration Technologies, LLC</b>
Location	Woodstock, GA, US
Contact	John Warlick
510(k) history	2 submissions · 2 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200926/> 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 26, 2026