FDA 510(k) Premarket Notification

K200926 OrthoGold 100

CLEARED

Aug 28, 2020
143 days to decision

K200926 · Product code: **PZL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200926/

SUBMISSION DETAILS

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

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