FDA 510(k) Premarket Notification

K191961 OrthoGold

CLEARED

Nov 26, 2019
126 days to decision

K191961 · Product code: **PZL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal Shock Wave Device For Treatment Of Diabetic Foot Ulcers (PZL)
Date received	Jul 23, 2019
Decision date	Nov 26, 2019
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tissue Regeneration Technologies**
Location	Woodstock, GA, US
Contact	John Warlick
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Jennifer A Daudelin

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