

K213120 OW100S (model OW100S-US)Oct 12, 2022
380 days to decisionK213120 · Product code: **ISA** · Physical Medicine
Source: <https://www.510kdatabase.net/k213120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Therapeutic, Electric (ISA)
Date received	Sep 27, 2021
Decision date	Oct 12, 2022
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tissue Regeneration Technologies, LLC DbA AS Softwave Trt
Location	Woodstock, GA, US
Contact	John Warlick
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Msquared Associates, Inc.
Contact	Cherita James

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

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