

K191568 sam 2.0 Long Duration Ultrasound SystemMar 6, 2020
267 days to decisionK191568 · Product code: **PFW** · Physical Medicine
Source: <https://www.510kdatabase.net/k191568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stationary Ultrasonic Diathermy Device For Use In Applying Therapeutic Deep Heat (PFW)
Date received	Jun 13, 2019
Decision date	Mar 6, 2020
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ZetrOZ Systems, LLC
Location	Trumbull, CT, US
Contact	Sabrina Lewis
Website	https://zetroz.com
510(k) history	5 submissions · 5 cleared · 2020-2026

ZetrOZ Systems, LLC is a medical device manufacturer headquartered in Trumbull, Connecticut. The company develops and manufactures wearable ultrasound devices for non-invasive tissue healing and pain management. ZetrOZ specializes in sustained acoustic medicine (sam®) technology for acute and chronic musculoskeletal conditions. ZetrOZ has received FDA 510(k) clearances from total submissions since its first clearance in 2020. The company focuses exclusively on Physical Medicine devices. Its latest FDA 510(k) clearance was in 2026, demonstrating continued regulatory activi...
