

K211513 sam X1 Long Duration Ultrasound DeviceAug 18, 2021
96 days to decisionK211513 · Product code: **PFW** · Physical Medicine
Source: <https://www.510kdatabase.net/k211513/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stationary Ultrasonic Diathermy Device For Use In Applying Therapeutic Deep Heat (PFW)
Date received	May 14, 2021
Decision date	Aug 18, 2021
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	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...