

**K260076 SAM 3.0 Multi-Hour Continuous Ultrasound Device**Apr 28, 2026  
106 days to decisionK260076 · Product code: **PFW** · Physical Medicine  
Source: <https://www.510kdatabase.net/k260076/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stationary Ultrasonic Diathermy Device For Use In Applying Therapeutic Deep Heat (PFW)
Date received	Jan 12, 2026
Decision date	Apr 28, 2026
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ZetrOZ Systems, LLC</b>
Location	Trumbull, CT, US
Contact	Sabrina Lewis
Website	<a href="https://zetroz.com">https://zetroz.com</a>
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...