

K250434 trophon2Aug 5, 2025
172 days to decisionK250434 · Product code: **OJJ** · General Hospital
Source: <https://www.510kdatabase.net/k250434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Mist (OUJ)
Date received	Feb 14, 2025
Decision date	Aug 5, 2025
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanosonics
Location	Macquarie Park, AU
Contact	Nancy Kaiser
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026