

**K250684 OPUSWAVE Dual Sensor Imaging System**Jul 2, 2025  
118 days to decisionK250684 · Product code: **NQQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Mar 6, 2025
Decision date	Jul 2, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Cardiovascular Systems Thi Plant</b>
Location	Ann Arbor, MI, US
Contact	Rahul Reddy Chinkeri
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250684/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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