

**K253459 OPTIS Mobile Next Imaging System (1014932)**Apr 24, 2026  
199 days to decisionK253459 · Product code: **NQQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Oct 7, 2025
Decision date	Apr 24, 2026
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	OPTIS Integrated Next Imaging System (1014933); Ultrason 3.0 Software Upgrade Kit (ULTR300001)

**APPLICANT**

Company	<b>Abbott Medical</b>
Location	S,Mta Clara, CA, US
Contact	Derek Pike
Website	<a href="https://www.abbott.com">https://www.abbott.com</a>
510(k) history	57 submissions · 57 cleared · 2019-2026

Abbott Medical is a global healthcare technology company headquartered in Santa Clara, US. The company specializes in life-changing medical devices and diagnostic solutions across multiple therapeutic areas. Abbott Medical maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. The company's primary focus is Cardiovascular devices, which represent 94% of its submission portfolio. Clearances span from 2019 to 2026, with recent activity demonstrating continued innovation in interventional cardiology and electrophysiology systems. R...

**CLINICAL EVIDENCE - NCT04356027****FUnctional diagnoSIs of corONary Stenosis (FUSION)**

Status	Completed
Enrollment	312 patients (actual)
Study sites	28 sites
Condition studied	Coronary Artery Disease; Coronary Stenosis
Study type	Observational
Completion date	Oct 15, 2021
Sponsor	Abbott Medical Devices (Industry)

**Primary outcome**

Sensitivity and Specificity of Virtual Flow Reserve (VFR) Against Fractional Flow Reserve (FFR)

**Secondary outcome****Overall Diagnostic Accuracy**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04356027](https://clinicaltrials.gov/study/NCT04356027)