

K232386 ILUMIEN™ OPTIS™ System, OPTIS™ Integrated System, OPTIS™ Mobile System, with AptiVue™ Imaging Software version E.6Sep 8, 2023
30 days to decisionK232386 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k232386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Aug 9, 2023
Decision date	Sep 8, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Medical
Location	S,Mta Clara, CA, US
Contact	Derek Pike
Website	https://www.abbott.com
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...