

K210458 OPTIS Mobile Next Imaging System, OPTIS Integrated Next Imaging System

Jun 8, 2021
112 days to decision

K210458 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k210458/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Feb 16, 2021
Decision date	Jun 8, 2021
Days to decision	112 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	Steve Vitale
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...