

K242098 Cornaris Intravascular Imaging System (P80-E)Apr 11, 2025
267 days to decisionK242098 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k242098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Jul 18, 2024
Decision date	Apr 11, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Cornaris Intravascular Imaging System (Mobile-E); LumenCross Imaging Catheter (F2)

APPLICANT

Company	Shenzhen Vivolight Medical Device & Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Gao Pengyang
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242098/> 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 13, 2026