

K233948 Provisio™ SLT IVUS™ SystemApr 23, 2024
131 days to decisionK233948 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k233948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Dec 14, 2023
Decision date	Apr 23, 2024
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Provisio Medical, Inc.
Location	San Diego, CA, US
Contact	Robert Ashley
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Veranex, Inc.
Contact	Zane Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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