FDA 510(k) Premarket Notification

K233948 Provisio™ SLT IVUS™ System

CLEARED

Apr 23, 2024
131 days to decision

K233948 · 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