CLEARED

K242966 Gentuity® HF-OCT Imaging System with Vis-Rx Prime® Micro-Imaging Catheter

Jan 31, 2025
127 days to decision

K242966 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k242966/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 26, 2024
Decision date	Jan 31, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gentuity, LLC**
Location	Sudbury, MA, US
Contact	Edwin Rule
510(k) history	4 submissions · 4 cleared · 2020-2025