

**K242239 HF-OCT Imaging System with Vis-RX Micro-Imaging Catheter (G10 (HF-OCT Console), G30 (Vis-Rx Micro-Imaging Catheter))**Aug 16, 2024  
17 days to decisionK242239 · Product code: **NQQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242239/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Jul 30, 2024
Decision date	Aug 16, 2024
Days to decision	17 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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