

**K230620 Gentuity® HF-OCT Imaging System with Vis-Rx®
Micro-Imaging Catheter**Aug 8, 2023
155 days to decisionK230620 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k230620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Mar 6, 2023
Decision date	Aug 8, 2023
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230620/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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