

K192922 Genuity HF-OCT Imaging System with Vis-Rx Micro-Imaging CatheterFeb 20, 2020
127 days to decisionK192922 · Product code: **NQQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k192922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Oct 16, 2019
Decision date	Feb 20, 2020
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genuity, LLC
Location	Sudbury, MA, US
Contact	David Kolstad
510(k) history	4 submissions · 4 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192922/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026