

**K242966 Genuity® HF-OCT Imaging System with Vis-Rx Prime® Micro-Imaging Catheter**Jan 31, 2025  
127 days to decisionK242966 · 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        | <b>Genuity, LLC</b>                   |
| Location       | Sudbury, MA, US                       |
| Contact        | Edwin Rule                            |
| 510(k) history | 4 submissions · 4 cleared · 2020-2025 |

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242966/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026