

**K123274 PROGASTRO SSCS ASSAY**Jan 16, 2013  
89 days to decisionK123274 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k123274/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH) |
| Date received         | Oct 19, 2012  |
| Decision date         | Jan 16, 2013  |
| Days to decision      | 89 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Gen-Probe Prodesse, Inc.</b>         |
| Location       | Waukesha, WI, US                        |
| Contact        | KAREN HARRINGTON                        |
| 510(k) history | 10 submissions · 10 cleared · 2010-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123274/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026