

**K201741 Gabriel 3 Way EnFit Valve**Nov 5, 2020  
133 days to decisionK201741 · Product code: **PIF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k201741/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Gastrointestinal Tubes With Enteral Specific Connectors (PIF) |
| Date received         | Jun 25, 2020  |
| Decision date         | Nov 5, 2020   |
| Days to decision      | 133 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Syncro Medical Innovations, Inc.</b> |
| Location       | Macon, GA, US                           |
| Contact        | Sabry Gabriel                           |
| 510(k) history | 6 submissions · 3 cleared · 2002-2020   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201741/> 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 18, 2026