

**K100947 FINESSE PERSONAL INSULIN DELIVERY PATCH,  
MODEL FG 2000**Jun 28, 2010  
83 days to decisionK100947 · Product code: **OPP** · General Hospital  
Source: <https://www.510kdatabase.net/k100947/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special                             |
| Device classification | Pump, Infusion, Insulin Bolus (OPP) |
| Date received         | Apr 6, 2010                         |
| Decision date         | Jun 28, 2010                        |
| Days to decision      | 83 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Calibra Medical, Inc.</b>          |
| Location       | Redwood City, CA, US                  |
| Contact        | RICHARD J MEADER                      |
| 510(k) history | 3 submissions · 3 cleared · 2010-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100947/>; 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 15, 2026