

**K222398 Care Team Portal**Feb 6, 2023  
182 days to decisionK222398 · Product code: **DRG** · Cardiovascular  
Source: <https://www.510kdatabase.net/k222398/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                     |
| Submission type       | Traditional  |
| Device classification | Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG) |
| Date received         | Aug 8, 2022  |
| Decision date         | Feb 6, 2023  |
| Days to decision      | 182 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Vivify Health, Inc.</b>            |
| Location       | Plano, TX, US                         |
| Contact        | Tracey Fox                            |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Hogan Lovells US LLP</b> |
| Contact         | Jodi Scott                  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222398/> 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 27, 2026