

**K193631 Stethee Pro 1, Stethee Pro Software System**Oct 9, 2020  
287 days to decisionK193631 · Product code: **DQD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k193631/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Stethoscope, Electronic (DQD)      |
| Date received         | Dec 27, 2019                       |
| Decision date         | Oct 9, 2020                        |
| Days to decision      | 287 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>M3Dicine Pty , Ltd.</b>            |
| Location       | Brisbane, AU                          |
| Contact        | Nayyar Hussain                        |
| 510(k) history | 2 submissions · 2 cleared · 2017-2020 |

**REGULATORY CONSULTANT**

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|-----------------|--------------------------------|
| Consulting firm | <b>Centaur Consulting, LLC</b> |
| Contact         | Ginger Cantor                  |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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