

**K192100 Aveta Disposable Hysteroscope**Dec 19, 2019  
136 days to decisionK192100 · Product code: **HIH** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k192100/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Special                              |
| Device classification | Hysteroscope (and Accessories) (HIH) |
| Date received         | Aug 5, 2019                          |
| Decision date         | Dec 19, 2019                         |
| Days to decision      | 136 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Meditrina, Inc.</b>                |
| Location       | Cupertino, CA, US                     |
| Contact        | Csaba Truckai                         |
| 510(k) history | 5 submissions · 5 cleared · 2019-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192100/> 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 May 27, 2026