

**K143650 CooperSurgical Advincula Delineator Uterine Manipulator**Jul 21, 2015  
210 days to decisionK143650 · Product code: **HEW** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k143650/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Culdoscope (and Accessories) (HEW) |
| Date received         | Dec 23, 2014                       |
| Decision date         | Jul 21, 2015                       |
| Days to decision      | 210 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>CooperSurgical, Inc.</b>             |
| Location       | Mountain View, CA, US                   |
| Contact        | James Keller                            |
| 510(k) history | 41 submissions · 40 cleared · 1991-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143650/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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