

K181124 Acesa ProVu SystemSep 28, 2018
151 days to decisionK181124 · Product code: **HFG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k181124/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Coagulator, Laparoscopic, Unipolar (and Accessories) (HFG) |
| Date received | Apr 30, 2018 |
| Decision date | Sep 28, 2018 |
| Days to decision | 151 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Acesa Health, Inc. |
| Location | Austin, TX, US |
| Contact | Brian J. Bergeron |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181124/> Data sourced from FDA 510(k) public records (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. - Generated June 20, 2026