

K223866 Carevix™ Suction Cervical StabilizerJan 25, 2023
33 days to decisionK223866 · Product code: **HDC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k223866/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Tenaculum, Uterine (HDC) |
| Date received | Dec 23, 2022 |
| Decision date | Jan 25, 2023 |
| Days to decision | 33 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Aspivix SA |
| Location | Renens, CH |
| Contact | Mauro Rinaldi |
| 510(k) history | 2 submissions · 2 cleared · 2021-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223866/> 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 May 26, 2026