

K203820 ASPIVIX v1.1 Cervical Suction TenaculumAug 17, 2021
231 days to decisionK203820 · Product code: **HDC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k203820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tenaculum, Uterine (HDC)
Date received	Dec 29, 2020
Decision date	Aug 17, 2021
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203820/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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