

K211959 Milli Vaginal DilatorDec 1, 2021
160 days to decisionK211959 · Product code: **HDX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Jun 24, 2021
Decision date	Dec 1, 2021
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Materna Medical
Location	Mountain View, CA, US
Contact	Kelly Ashfield
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Experien Group, LLC
Contact	Valerie Defiesta-Ng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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