FDA 510(k) Premarket Notification

K211959 Milli Vaginal Dilator

CLEARED

Dec 1, 2021
160 days to decision

K211959 · Product code: **HDX** · Obstetrics & Gynecology
Source: 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