FDA 510(k) Premarket Notification

K220035 Milli Vaginal Dilator

CLEARED

Feb 27, 2023
418 days to decision

K220035 · Product code: **HDX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k220035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Jan 5, 2022
Decision date	Feb 27, 2023
Days to decision	418 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	**Domecus Consulting Services, LLC**
Contact	Cindy Domecus

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