

K201403 NATtrol BD MAX Vaginal Panel External Controls

Feb 2, 2022
615 days to decision

K201403 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k201403/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	May 28, 2020
Decision date	Feb 2, 2022
Days to decision	615 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zeptomatrix
Location	Buffalo, NY, US
Contact	Shawn Smith
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	MDC Associates, Inc.
Contact	Michael Smith

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