FDA 510(k) Premarket Notification

K202542 Allura Vaginal Stent

CLEARED

Sep 30, 2020
28 days to decision

K202542 · Product code: **KXP** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k202542/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Vaginal (KXP)
Date received	Sep 2, 2020
Decision date	Sep 30, 2020
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Pmt Corporation**
Location	Chanhassen, MN, US
Contact	Matt Cree
510(k) history	2 submissions · 2 cleared · 2016-2020

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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