FDA 510(k) Premarket Notification

K181034 Pocket Colposcope System

CLEARED

Sep 21, 2018
156 days to decision

K181034 · Product code: **HEX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k181034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Apr 18, 2018
Decision date	Sep 21, 2018
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hadleigh Health Technologies, LLC**
Location	San Rafael, CA, US
Contact	Robert Miros
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	**University of Utah**
Contact	Spencer Walker

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