CLEARED

K192034 HDX 100% Silicone 2-way Foley Catheter, 14Fr/10cc, HDX 100% Silicone 2-way Foley Catheter, 16Fr/5cc, HDX 100% Silicone 2-way Foley Catheter, 18Fr/10cc

Apr 21, 2020
266 days to decision

K192034 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k192034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 30, 2019
Decision date	Apr 21, 2020
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pathway, LLC**
Location	Santee, CA, US
Contact	David Stroup
510(k) history	3 submissions · 3 cleared · 2016-2020