

**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**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k192034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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