

**K200556 AquaFlate Pre-Filled Sterile Water Syringe 10mL**Mar 31, 2020  
28 days to decisionK200556 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k200556/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Mar 3, 2020
Decision date	Mar 31, 2020
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>H R Pharmaceuticals, Inc.</b>
Location	York, PA, US
Contact	Colby Wiesman
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200556/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026