

**K202566 Wiygul Catheter**Sep 30, 2020  
26 days to decisionK202566 · Product code: **EZD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k202566/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Sep 4, 2020
Decision date	Sep 30, 2020
Days to decision	26 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Big Blue Biotech, Inc.</b>
Location	Canton, MA, US
Contact	Russ Olsen
510(k) history	1 submissions · 1 cleared · 2020-2020

**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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