

**K210625 JAZZ Suction Valve, JAZZ Air/Water Valve, JAZZ Forceps Valve**Sep 10, 2021  
192 days to decisionK210625 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Mar 2, 2021
Decision date	Sep 10, 2021
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medwork GmbH</b>
Location	Hochstadt, DE
Contact	Randy Vader
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Contact	Jeffrey Wan

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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