

K213195 Balloon BS-3Oct 29, 2021
30 days to decisionK213195 · Product code: **FDA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enteroscope And Accessories (FDA)
Date received	Sep 29, 2021
Decision date	Oct 29, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	FUJIFILM Healthcare Americas Corporation
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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