FDA 510(k) Premarket Notification

K213195 Balloon BS-3

CLEARED

Oct 29, 2021
30 days to decision

K213195 · Product code: **FDA** · Gastroenterology & Urology
Source: 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