

**K223295 Endoscope Model EN-580T, Over-tube TS-1314B,
Balloon BS-4, Tube Kit TY-500D**Jan 11, 2023
77 days to decisionK223295 · Product code: FDA · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k223295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enteroscope And Accessories (FDA)
Date received	Oct 26, 2022
Decision date	Jan 11, 2023
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporaton
Location	Tokyo, JP
Contact	Randy Vader
510(k) history	6 submissions · 6 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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