

**K233321 Double Balloon Endoscope EN-840T, Over-tube
TS-1214C**Jun 13, 2024
258 days to decisionK233321 · Product code: FDA · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Sep 29, 2023
Decision date	Jun 13, 2024
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Healthcare Americas Corporation
Location	Lexington, MA, US
Contact	Chaitrali Kulkarni
510(k) history	12 submissions · 12 cleared · 2023-2025

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