

**K230752 Over-tube (TR-1208A)**Sep 15, 2023  
182 days to decisionK230752 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230752/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Mar 17, 2023
Decision date	Sep 15, 2023
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Over-tube (TR-1504A); Over-tube (TR-1507A)

**APPLICANT**

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Company	<b>Fujifilm Healthcare Americas Corporation</b>
Location	Lexington, MA, US
Contact	Kotei Aoki
510(k) history	12 submissions · 12 cleared · 2023-2025

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