

K251041 GripTract-GI™ Endoscopic Tissue Manipulator Upper GI Model GT-GS100

Oct 31, 2025
211 days to decision

K251041 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k251041/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Apr 3, 2025
Decision date	Oct 31, 2025
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Actuated Medical, Inc.
Location	Bellefonte, PA, US
Contact	Douglas Dillon
510(k) history	10 submissions · 10 cleared · 2012-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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