

**K253393 Single-use Balloon Dilatation Catheter**  
**(AG-5251-083018 AG-5251-085518 AG-5251-088018**  
**AG-5251-083019 AG-5251-085519 AG-5251-088019**  
**AG-5251-083021 AG-5251-085521 AG-5251-088021**  
**AG-5251-083024 AG-5251-085524 AG-5251-088024**  
**AG-5251-103018 AG-5251-105518 AG-5251-108018**  
**AG-5251-103019 AG-5251-105519 AG-5251-108019**  
**AG-5251-103021 AG-5251-105521 AG-5251-108021**  
**AG-5251-103024 AG-5251-105524 AG-5251-108024**  
**AG-5251-123018 AG-5251-125518 AG-5251-128018**  
**AG-5251-123019 AG-5251-125519 AG-5251-128019**

Jun 24, 2026  
 267 days to decision

K253393 · Product code: **FGE** · Gastroenterology & Urology  
 Source: <https://www.510kdatabase.net/k253393/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Sep 30, 2025
Decision date	Jun 24, 2026
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou AGS MedTech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Kai Zhang
510(k) history	18 submissions · 18 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k253393/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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