

K213578 Balloon Dilatation CatheterApr 6, 2022
147 days to decisionK213578 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k213578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Nov 10, 2021
Decision date	Apr 6, 2022
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou AGS MedTech Co., Ltd.
Location	Hangzhou, CN
Contact	Jiayuan Zhang
510(k) history	17 submissions · 17 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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