FDA 510(k) Premarket Notification

K213578 Balloon Dilatation Catheter

CLEARED

Apr 6, 2022
147 days to decision

K213578 · Product code: **FDF** · Gastroenterology & Urology
Source: 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