

**K222421 Sphincterotome**May 3, 2023  
265 days to decisionK222421 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Aug 11, 2022
Decision date	May 3, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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