

**K201121 Sphincterotome**Feb 5, 2021  
284 days to decisionK201121 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201121/>**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	Apr 27, 2020
Decision date	Feb 5, 2021
Days to decision	284 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	Chunqi Han
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/k201121/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026