

**K190032 Disposable Sclerotherapy Needle**Feb 27, 2020  
416 days to decisionK190032 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190032/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jan 7, 2019
Decision date	Feb 27, 2020
Days to decision	416 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	Xiangyong Yu
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/k190032/> 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