

**K212668 Sclerotherapy Needle**Feb 23, 2022  
184 days to decisionK212668 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k212668/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Aug 23, 2021
Decision date	Feb 23, 2022
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Chuangxiang Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Lucius Long
510(k) history	13 submissions · 13 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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