

K181690 Clear-Jet Injection CatheterDec 21, 2018
178 days to decisionK181690 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181690/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jun 26, 2018
Decision date	Dec 21, 2018
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Finemedix Co., Ltd.
Location	Daegu, KR
Contact	Hee Kyung Kwon
510(k) history	11 submissions · 11 cleared · 2018-2026

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