

K241523 injeTAK Adjustable Tip Needle (DIS199)Aug 27, 2024
90 days to decisionK241523 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k241523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	May 29, 2024
Decision date	Aug 27, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DIS201)

APPLICANT

Company	Laborie Medical Technologies, Corp.
Location	Williston, VT, US
Contact	Thomas Hirte
510(k) history	5 submissions · 5 cleared · 2008-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241523/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026