

K132065 INJECTION NEEDLEJan 17, 2014
198 days to decisionK132065 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k132065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 3, 2013
Decision date	Jan 17, 2014
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Endochoice, Inc.
Location	Chalotte, NC, US
Contact	THERON GOBER
510(k) history	27 submissions · 25 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132065/> 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 June 7, 2026