

K190829 Gastrointestinal Injection Needles (VIN, LDVI, DVI and MHI)

Dec 19, 2019
262 days to decision

K190829 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190829/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Apr 1, 2019
Decision date	Dec 19, 2019
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical Inc./Cook Endoscopy
Location	Winstrom-Salem, NC, US
Contact	Tiffany A Thomas
510(k) history	7 submissions · 7 cleared · 2012-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190829/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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