

K180214 Repris Bladder Injection SystemMay 3, 2018
98 days to decisionK180214 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jan 25, 2018
Decision date	May 3, 2018
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Uro-1, Inc.
Location	Winston Salem, NC, US
Contact	Thomas Lawson
510(k) history	3 submissions · 3 cleared · 2018-2022

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