

**K222006 Sclerotherapy & Endoscopic Needles**Apr 3, 2023  
270 days to decisionK222006 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k222006/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 7, 2022
Decision date	Apr 3, 2023
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>G-Flex Europe Sprl</b>
Location	Nivelles, BE
Contact	Thierry Cremer
510(k) history	2 submissions · 2 cleared · 2022-2023

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