

**K001146 GENYX FLEXIBLE INJECTION NEEEDLE**Jun 30, 2000  
81 days to decisionK001146 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k001146/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Apr 10, 2000
Decision date	Jun 30, 2000
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Geny Medical, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	JUDY F GORDON
510(k) history	2 submissions · 2 cleared · 1979-2000

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