

**K081956 MEDINOL X-SUIT NIR BILIARY METALLIC STENT**Jan 9, 2009  
184 days to decisionK081956 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k081956/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 9, 2008
Decision date	Jan 9, 2009
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Medinol, Ltd.</b>
Location	Tel-Aviv, IL
Contact	LEO L BASTA
510(k) history	6 submissions · 3 cleared · 1998-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081956/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 31, 2026