

K150487 X-Suit NIR Biliary Metallic StentFeb 12, 2016
352 days to decisionK150487 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k150487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 25, 2015
Decision date	Feb 12, 2016
Days to decision	352 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medinol, Ltd.
Location	Tel-Aviv, IL
Contact	Michal Hershkovitz
510(k) history	6 submissions · 3 cleared · 1998-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150487/> Data sourced from FDA 510(k) public records (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. - Generated May 31, 2026