

K973171 NIR BILIARY STENTNov 13, 1998
445 days to decisionK973171 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k973171/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Aug 25, 1997 |
| Decision date | Nov 13, 1998 |
| Days to decision | 445 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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