

**K945498 INSTENT ENDOCOIL-T(TM) TRANSHEPATIC BILIARY
ENDOPROSTHESIS**Sep 12, 1995
308 days to decisionK945498 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k945498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Nov 8, 1994
Decision date	Sep 12, 1995
Days to decision	308 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Instent, Inc.
Location	Eden Prairie, MN, US
Contact	KARL GROTH
510(k) history	4 submissions · 4 cleared · 1995-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945498/> 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 July 1, 2026