

K990808 PBN DILATORSNov 26, 1999
260 days to decisionK990808 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 11, 1999
Decision date	Nov 26, 1999
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Device Technologies, Inc.
Location	Gainesville, FL, US
Contact	KARL SWARTZ
510(k) history	46 submissions · 46 cleared · 1992-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990808/> 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 20, 2026