

K990854 INNERDYNE RADially EXPANDING DILATION, RED DEVICEAug 2, 1999
140 days to decisionK990854 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k990854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Mar 15, 1999
Decision date	Aug 2, 1999
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innerdyne, Inc.
Location	Salt Lake City, UT, US
Contact	RICK GAYKOWSKI
510(k) history	12 submissions · 12 cleared · 1995-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990854/> 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