FDA 510(k) Premarket Notification

K990854 INNERDYNE RADIALLY EXPANDING DILATION, RED DEVICE

CLEARED

Aug 2, 1999
140 days to decision

K990854 · 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