FDA 510(k) Premarket Notification

K992816 MODIFICATION TO INTRASTENT

CLEARED

Oct 15, 1999
56 days to decision

K992816 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k992816/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Aug 20, 1999
Decision date	Oct 15, 1999
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Intratherapeutics, Inc.**
Location	Saint Paul, MN, US
Contact	CATHY YOHNK
510(k) history	15 submissions · 7 cleared · 1998-2001