FDA 510(k) Premarket Notification

K913113 FST CATH-UD CATHETER, MODIFICATION

CLEARED

Oct 9, 1991
96 days to decision

K913113 · Product code: **FEN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k913113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Jul 5, 1991
Decision date	Oct 9, 1991
Days to decision	96 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Fiberoptic Sensor Technlogies, Inc.**
Location	Plymouth, MI, US
Contact	DOUGLAS G TOMASKO
510(k) history	11 submissions · 11 cleared · 1987-1995