FDA 510(k) Premarket Notification

K901603 MODIFIED PORGES SPEC 5* SUPRAPUBIC CATHETER

CLEARED

May 4, 1990
38 days to decision

K901603 · Product code: **KOB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k901603/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Mar 27, 1990
Decision date	May 4, 1990
Days to decision	38 days
Third-party review	No

APPLICANT

Company	**Bivona Medical Technologies**
Location	Mchenry, IL, US
Contact	HARRY M KAUFMAN
510(k) history	50 submissions · 50 cleared · 1978-1995