FDA 510(k) Premarket Notification

K980980 MOTILITY PROBE MODEL NUMBERS P31 THRU P38, P40 THRU P43 AND P50

CLEARED

Jun 15, 1998
90 days to decision

K980980 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k980980/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Mar 17, 1998
Decision date	Jun 15, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Konigsberg Instruments, Inc.**
Location	Walker, MI, US
Contact	ARLIN HANSON
510(k) history	3 submissions · 3 cleared · 1981-1998