FDA 510(k) Premarket Notification

K082056 ANORECTAL MANOMETRY SOFTWARE OPTION ARM-1

CLEARED

Nov 7, 2008
109 days to decision

K082056 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k082056/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 21, 2008
Decision date	Nov 7, 2008
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Life-Tech, Inc.**
Location	Stafford, TX, US
Contact	JEFF KASOFF
510(k) history	14 submissions · 14 cleared · 2005-2012