FDA 510(k) Premarket Notification

CLEARED

K091070 MANOSCAN MOTILITY WITH IMPEDANCE VISUALIZATION SYSTEM

May 19, 2009
35 days to decision

K091070 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k091070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Apr 14, 2009
Decision date	May 19, 2009
Days to decision	35 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Sierra Scientific Instruments, Inc.**
Location	San Diego, CA, US
Contact	REIC S FINKELMAN
510(k) history	2 submissions · 2 cleared · 2003-2009