FDA 510(k) Premarket Notification

K012232 INSIGHT, MODEL S980000

CLEARED

Jun 7, 2002
326 days to decision

K012232 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 16, 2001
Decision date	Jun 7, 2002
Days to decision	326 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sandhill Scientific, Inc.**
Location	Mchenry, IL, US
Contact	LEWIS WARD
510(k) history	16 submissions · 16 cleared · 1984-2011