FDA 510(k) Premarket Notification

K004040 REDTECH GIPC 2000

CLEARED

Mar 29, 2001
90 days to decision

K004040 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k004040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Dec 29, 2000
Decision date	Mar 29, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Red-Tech, Inc.**
Location	Laguna Niguel, CA, US
Contact	GARY MOCNIK
510(k) history	1 submissions · 1 cleared · 2001-2001