FDA 510(k) Premarket Notification

K011270 AUTOMATED CORE BIOPSY DEVICE

CLEARED

Jun 22, 2001
57 days to decision

K011270 · Product code: **FCG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k011270/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Apr 26, 2001
Decision date	Jun 22, 2001
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Promex, Inc.**
Location	Indianapolis, IN, US
Contact	JOSEPH L MARK
510(k) history	18 submissions · 18 cleared · 1994-2002