FDA 510(k) Premarket Notification

K010400 VACUUM ASSISTED CORE BIOPSY DEVICE

CLEARED

Jul 24, 2001
162 days to decision

K010400 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k010400/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 12, 2001
Decision date	Jul 24, 2001
Days to decision	162 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