FDA 510(k) Premarket Notification

CLEARED

K012224 SINGLE ACTION BIOPSY NEEDLE, MODEL RCBS: XX GAUGE, XX LENGTH, XX THROW

Aug 22, 2001
67 days to decision

K012224 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k012224/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jun 16, 2001
Decision date	Aug 22, 2001
Days to decision	67 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ranfac, Corp.**
Location	Avon, MA, US
Contact	GEORGE J HATTUB
510(k) history	12 submissions · 12 cleared · 1985-2017