FDA 510(k) Premarket Notification

CLEARED

K093399 PRECISECORE 10 MM BIOPSY DEVICE- 14GA X 5 CM MODEL 670514, 671014, 670518 671018, 670520

Nov 19, 2009
17 days to decision

K093399 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 2, 2009
Decision date	Nov 19, 2009
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Inrad**
Location	Kentwood, MI, US
Contact	MELISSA LALOMIA
510(k) history	11 submissions · 11 cleared · 1998-2009