FDA 510(k) Premarket Notification

K080171 SANARUS INCORE ROTATIONAL CORE BIOPSY DEVICE, MODELS CB3010, CB3012

CLEARED

Mar 6, 2008
42 days to decision

K080171 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k080171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jan 24, 2008
Decision date	Mar 6, 2008
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sanarus Medical, Inc.**
Location	Pleasanton, CA, US
Contact	LISA HENRY
510(k) history	14 submissions · 14 cleared · 2002-2008