FDA 510(k) Premarket Notification

K021707 SINGLE STEP BIOPSY DEVICE, SINGLE STEP SURGICAL HANDLE, SINGLE STEP DRIVER, SINGLE STEP HOLDERS

CLEARED

Aug 14, 2002
83 days to decision

K021707 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k021707/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	May 23, 2002
Decision date	Aug 14, 2002
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Senorx, Inc.**
Location	Irvine, CA, US
Contact	AMY BOUCLY
510(k) history	30 submissions · 26 cleared · 2000-2023

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k021707/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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