FDA 510(k) Premarket Notification

K161805 EnCor MRI Introducer Set, EnCor Probe Introducer

CLEARED

Jul 19, 2016
18 days to decision

K161805 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161805/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 1, 2016
Decision date	Jul 19, 2016
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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