FDA 510(k) Premarket Notification

CLEARED

K233220 EnCor Enspire™Breast Biopsy System (E4115, E4230)

Oct 27, 2023
29 days to decision

K233220 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Sep 28, 2023
Decision date	Oct 27, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EnCor™ Breast Biopsy Driver (DRENCOR); EnCor™ MRI Breast Biopsy Driver (DRENCORMR); EnCor™ Breast Biopsy Driver Probes (ECP017G, ECP017GV, ECP0110G, ECP0110GV, ECP0112G, ECP0112GV); EnCor™ MRI Breast Biopsy Probes (ECPMR017G, ECPMR0110G, ECPMR0110GBT)

APPLICANT

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