FDA 510(k) Premarket Notification

K121950 MICROTARGETING XL STAR DRIVE SYSTEM

CLEARED

Jul 26, 2012
23 days to decision

K121950 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k121950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jul 3, 2012
Decision date	Jul 26, 2012
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**FHC, Inc.**
Location	Bowdoinham, ME, US
Contact	KERI SEITZ
510(k) history	12 submissions · 12 cleared · 2000-2023