FDA 510(k) Premarket Notification

K011992 FHC MICROTARGETING DRIVE SYSTEM

CLEARED

Aug 14, 2001
49 days to decision

K011992 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k011992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 26, 2001
Decision date	Aug 14, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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