

K231141 STarFix Designer Software C0265Sep 8, 2023
140 days to decisionK231141 · Product code: **QRI** · Neurology
Source: <https://www.510kdatabase.net/k231141/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Planning Software For Neurological Stereotaxic Instruments (QRI)
Date received	Apr 21, 2023
Decision date	Sep 8, 2023
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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