

**K233144 ClearPoint Bone Screw Fiducials**Jan 12, 2024  
107 days to decisionK233144 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k233144/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 27, 2023
Decision date	Jan 12, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ClearPoint Neuro, Inc.</b>
Location	Irvine, CA, US
Contact	Brennan Sullivan
510(k) history	12 submissions · 11 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233144/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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