

K250893 Ball Joint Guide Array (66295)Sep 4, 2025
163 days to decisionK250893 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k250893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Mar 25, 2025
Decision date	Sep 4, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Medical Care, Inc.
Location	Indianola, PA, US
Contact	Purva Pandya
510(k) history	9 submissions · 9 cleared · 2015-2026

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