

K213208 Twist DrillsDec 23, 2021
85 days to decisionK213208 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k213208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 29, 2021
Decision date	Dec 23, 2021
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Microfixation
Location	Jacksonville, FL, US
Contact	Mark Wladkowski
510(k) history	24 submissions · 24 cleared · 2012-2024

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Danielle Besal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213208/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026