

K213072 2.1 x 255mm Drill, 22mm StopAug 23, 2022
334 days to decisionK213072 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k213072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Sep 23, 2021
Decision date	Aug 23, 2022
Days to decision	334 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Micofixation
Location	Jacksonville, FL, US
Contact	Mark Wladkowski
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	MRC Global
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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