

K250423 mb-FIX Cranial Stabilization SystemsNov 6, 2025
265 days to decisionK250423 · Product code: **HBL** · Neurology
Source: <https://www.510kdatabase.net/k250423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	Feb 14, 2025
Decision date	Nov 6, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medical Bees GmbH
Location	Emmingen-Liptingen, DE
Contact	Laura Sperle
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Business Support International
Contact	Angelika Scherp

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

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