

**K243368 Montblanc Plate System**Jun 4, 2025  
217 days to decisionK243368 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k243368/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 30, 2024
Decision date	Jun 4, 2025
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medifield Medical Co., Ltd.</b>
Location	Pocheon-Si, KR
Contact	Bonggu Ha
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243368/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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