

**K213864 Bonebridge Osteosynthesis Plating System**Sep 2, 2022  
266 days to decisionK213864 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k213864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 10, 2021
Decision date	Sep 2, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bonebridge AG</b>
Location	Zug, CH
Contact	Christof Gerber
510(k) history	9 submissions · 9 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Meditec Consulting GmbH</b>
Contact	Sandra Soniec

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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