

**K203002 SALGINA 2.5mm Volar Distal Radius System,
CASCELLA 3.5mm Superior Clavicle System, TAMINA 3.5mm
Proximal Humerus System, TRIFT 3.5mm 1/3 Tubular System**Oct 5, 2021
369 days to decisionK203002 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k203002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Oct 1, 2020
Decision date	Oct 5, 2021
Days to decision	369 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Meditec Consulting GmbH
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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