

**K191641 AFFINITY – Variable Angle Distal Radius System,
AFFINITY – Variable Angle Distal Radius Plates, AFFINITY –
Variable Angle Distal Radius Screws**

Sep 16, 2019
89 days to decision

K191641 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k191641/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 19, 2019
Decision date	Sep 16, 2019
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Industrias Medicas Sampedro S.A.S
Location	La Estrella, CO
Contact	Liliana Zuluaga-Idarraga
510(k) history	2 submissions · 2 cleared · 2019-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191641/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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