

K182492 Geminus Volar Distal Radius Plate SystemOct 10, 2018
29 days to decisionK182492 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k182492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 11, 2018
Decision date	Oct 10, 2018
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skeletal Dynamics, LLC
Location	Shelton, CT, US
Contact	Ana M. Escagedo
510(k) history	18 submissions · 18 cleared · 2010-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026