

**K211650 The Radian MIS Bunion System**Nov 24, 2021  
180 days to decisionK211650 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k211650/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 28, 2021
Decision date	Nov 24, 2021
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Nvision Biomedical Technologies, Inc.</b>
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Nvision Biomedical Technologies</b>
Contact	Analaura Villarreal-Berain

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211650/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026