

**K241995 HyperFlex™ Bunion Correction System**Nov 26, 2024  
140 days to decisionK241995 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k241995/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 9, 2024
Decision date	Nov 26, 2024
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Footbridge Medical</b>
Location	Charlotte, NC, US
Contact	Robert Peterhans
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mcra, LLC</b>
Contact	Michael Coladonato

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241995/> 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 May 13, 2026