FDA 510(k) Premarket Notification

# K241995 HyperFlex™ Bunion Correction System

**CLEARED**

Nov 26, 2024
140 days to decision

K241995 · Product code: **HRS** · Orthopedic
Source: https://www.510kdatabase.net/k241995/

## SUBMISSION DETAILS

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|---|---|
| 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 | **Footbridge Medical** |
| Location | Charlotte, NC, US |
| Contact | Robert Peterhans |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mcra, LLC** |
| Contact | Michael Coladonato |

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