

K252997 HyperFlex® Bunion Correction SystemDec 11, 2025
84 days to decisionK252997 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k252997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 18, 2025
Decision date	Dec 11, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hyperflex Medical
Location	Port Huron, MI, US
Contact	Robert Peterhans
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Dave McGurl

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

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