

K253718 enHAnce PEEK Bunion SystemApr 1, 2026
128 days to decisionK253718 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k253718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 24, 2025
Decision date	Apr 1, 2026
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nvision Biomedical Technologies, Inc.
Location	San Antonio, TX, US
Contact	Marisa Zink
510(k) history	24 submissions · 24 cleared · 2019-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253718/> 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