

K202657 Javelin Tailor's Bunion Fixation SystemDec 14, 2020
91 days to decisionK202657 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k202657/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Sep 14, 2020 |
| Decision date | Dec 14, 2020 |
| Days to decision | 91 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 | Diana Langham |
| 510(k) history | 24 submissions · 24 cleared · 2019-2026 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Nvision Biomedical Technologies |
| 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.netDevice record: <https://www.510kdatabase.net/k202657/> 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 June 28, 2026