

K203595 DynaFuse Fixation SystemJan 4, 2022
391 days to decisionK203595 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k203595/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | Dec 9, 2020 |
| Decision date | Jan 4, 2022 |
| Days to decision | 391 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | MedShape, Inc. |
| Location | Atlanta, GA, US |
| Contact | Ryan O'Flaherty |
| 510(k) history | 16 submissions · 16 cleared · 2012-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203595/> 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 14, 2026