

K201510 Traufix osteosynthesis, osteotomy, and arthrodesis devicesFeb 18, 2022
623 days to decisionK201510 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k201510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 5, 2020
Decision date	Feb 18, 2022
Days to decision	623 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fixier S.A. DE C.V.
Location	Leon, MX
Contact	Vianey Mariana Perez Suarez
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Aurelia Brownridge
Contact	Aurelia Brownridge

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/k201510/> 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 27, 2026