

K200491 Bfix Orthopedic External Fixator SystemsJan 5, 2021
312 days to decisionK200491 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k200491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Feb 28, 2020
Decision date	Jan 5, 2021
Days to decision	312 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aike (Shanghai) Medical Instrument Co., Ltd.
Location	Shanghai, CN
Contact	Gu Hongying
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Landlink Medical Information Technology Co., Ltd.
Contact	Hongying Gu

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/k200491/> 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