

**K234042 EFAI Bonesuite XR Bone Age Pro Assessment System
(BAP-XR-100)**Jun 7, 2024
169 days to decisionK234042 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k234042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 21, 2023
Decision date	Jun 7, 2024
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ever Fortune.Ai, Co., Ltd.
Location	Taichung City, TW
Contact	Joseph Chang
510(k) history	15 submissions · 15 cleared · 2021-2026

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