

K253155 Fule Metallic Lockable Intramedullary Nail SystemsJun 17, 2026
264 days to decisionK253155 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k253155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 26, 2025
Decision date	Jun 17, 2026
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Fule Science & Technology Development Co., Ltd.
Location	Beijing, CN
Contact	Xiaoliang Chen
510(k) history	3 submissions · 3 cleared · 2025-2026

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