

**K252458 Kyphoplasty Balloon Dilatation Catheters**Nov 3, 2025  
90 days to decisionK252458 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k252458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Aug 5, 2025
Decision date	Nov 3, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Lange Medtech Co., Ltd.</b>
Location	Shanghai, CN
Contact	Zhou Xin
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Mil-Medshare Medical Technology Co., Ltd.</b>
Contact	Chen Kevin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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