FDA 510(k) Premarket Notification

K252458 Kyphoplasty Balloon Dilatation Catheters

CLEARED

Nov 3, 2025
90 days to decision

K252458 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k252458/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Shanghai Mil-Medshare Medical Technology Co., Ltd.**
Contact	Chen Kevin

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