

K223709 Kyphoplasty Balloon CatheterAug 16, 2023
247 days to decisionK223709 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k223709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Dec 12, 2022
Decision date	Aug 16, 2023
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Changmei Medtech Co., Ltd.
Location	Changzhou, CN
Contact	Yang Lifan
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Amber Pang

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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