FDA 510(k) Premarket Notification

K223709 Kyphoplasty Balloon Catheter

CLEARED

Aug 16, 2023
247 days to decision

K223709 · 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.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov