

**K221142 Kyphoplasty Balloon System**Apr 21, 2023  
367 days to decisionK221142 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k221142/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 19, 2022
Decision date	Apr 21, 2023
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OK Medinet Korea Co., Ltd.</b>
Location	Seoul, KR
Contact	Kang Yoo Jin
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Onbix Corporation</b>
Contact	Yang Ho Dong

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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