

K200763 Osteo-site Vertebral BalloonAug 12, 2020
141 days to decisionK200763 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k200763/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Mar 24, 2020
Decision date	Aug 12, 2020
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Izi Medical
Location	Owings Mills, MD, US
Contact	Qiang Cao
510(k) history	1 submissions · 1 cleared · 2020-2020

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