

K202027 Balex bone Expander SystemFeb 3, 2021
196 days to decisionK202027 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k202027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 22, 2020
Decision date	Feb 3, 2021
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taeyeon Medical Co., Ltd.
Location	Incheon, KR
Contact	Sin-Ae Kang
510(k) history	3 submissions · 3 cleared · 2007-2022

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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