

K182287 MEDINAUT PlusApr 6, 2019
226 days to decisionK182287 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k182287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Aug 23, 2018
Decision date	Apr 6, 2019
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imedicom Co., Ltd.
Location	Gunpo-Si, KR
Contact	Bonggu Ha
510(k) history	6 submissions · 6 cleared · 2016-2019

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182287/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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