FDA 510(k) Premarket Notification

K182287 MEDINAUT Plus

CLEARED

Apr 6, 2019
226 days to decision

K182287 · 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