FDA 510(k) Premarket Notification

K233800 Vertos mild Device Kit (MDK-0002)

CLEARED

May 6, 2024
159 days to decision

K233800 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k233800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Nov 29, 2023
Decision date	May 6, 2024
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vertos Medical, Inc.**
Location	Aliso Viejo, CA, US
Contact	Russ Alexander
Website	http://www.vertosmed.com/
510(k) history	1 submissions · 1 cleared · 2024-2024

Vertos Medical, Inc. develops orthopedic devices with a manufacturing facility in Aliso Viejo, California. The company specializes in minimally invasive spine surgery solutions. Vertos Medical has received FDA 510(k) clearance from total submission. The company's regulatory activity is focused entirely on orthopedic devices. The latest clearance was in 2024, confirming active development and market engagement. The company's cleared device portfolio includes the Vertos mild Device Kit (MDK-0002), a minimally invasive lumbar decompression system designed to relieve pain and...