FDA 510(k) Premarket Notification

K202771 CD Horizon Spinal System

CLEARED

Oct 19, 2020
28 days to decision

K202771 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k202771/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 21, 2020
Decision date	Oct 19, 2020
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	Raphael McInnis
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...