FDA 510(k) Premarket Notification

K032033 CD HORIZON SPINAL SYSTEM

CLEARED

Sep 12, 2003
73 days to decision

K032033 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k032033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 1, 2003
Decision date	Sep 12, 2003
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Sofamor Danek**
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	154 submissions · 147 cleared · 2002-2021