FDA 510(k) Premarket Notification

K252729 Universal Spinal System

CLEARED

Nov 18, 2025
82 days to decision

K252729 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k252729/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 28, 2025
Decision date	Nov 18, 2025
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Double Medical Technology, Inc.**
Location	Xiamen, CN
Contact	Joy Zuo
510(k) history	12 submissions · 12 cleared · 2016-2025