

K252346 OLYMPIC Posterior Spinal Fixation SystemOct 21, 2025
85 days to decisionK252346 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k252346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 28, 2025
Decision date	Oct 21, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MASADA Modular Spinal Fixation System

APPLICANT

Company	Astura Medical
Location	Carlsbad, CA, US
Contact	Parker Kelch
510(k) history	21 submissions · 21 cleared · 2016-2026

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