

**K181824 CBT Screw Fixation System**Dec 13, 2018  
157 days to decisionK181824 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k181824/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Jul 9, 2018
Decision date	Dec 13, 2018
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>U&amp;I Corporation</b>
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	Jee-Ae Bang
510(k) history	23 submissions · 23 cleared · 2013-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181824/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026