

K183383 ANAX™ OCT Spinal SystemDec 12, 2018
6 days to decisionK183383 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k183383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Posterior Cervical Screw System (NKG)
Date received	Dec 6, 2018
Decision date	Dec 12, 2018
Days to decision	6 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U&I Corporation
Location	Uijeongbu-Si, Gyeonggi-Do, KR
Contact	Young Eun Lee
510(k) history	23 submissions · 23 cleared · 2013-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183383/> Data sourced from FDA 510(k) public records (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. - Generated May 15, 2026