

K162189 ANAX™ 5.5 Spinal SystemAug 30, 2016
26 days to decisionK162189 · Product code: **MNH** · Orthopedic
Source: <https://www.510kdatabase.net/k162189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Aug 4, 2016
Decision date	Aug 30, 2016
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162189/> 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