

K130073 MIKRON SPINAL FIXATION SYSTEM, POLYXIAL PEDICLE SCREWS, SET SCREWS, LONGITUDINAL RODSDec 16, 2013
339 days to decisionK130073 · Product code: MNI · Orthopedic
Source: <https://www.510kdatabase.net/k130073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Jan 11, 2013
Decision date	Dec 16, 2013
Days to decision	339 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mikron Makina Sanayi VE Ticaret Ltd. Sti.
Location	Chesapeake City, MD, US
Contact	OMAR DIKER
510(k) history	3 submissions · 3 cleared · 2013-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130073/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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