

K190895 MOUNTAINEER OCT Spinal System, SUMMIT SI OCT Spinal Fixation System, SYMPHONY OCT System, SUMMIT Fixation System

Jul 18, 2019
104 days to decision

K190895 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k190895/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Apr 5, 2019
Decision date	Jul 18, 2019
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Sheree Geller
510(k) history	96 submissions · 96 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k190895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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