

K192281 AEGIS Anterior Lumbar Plate System, ALC Dynamized Fixation System, Anterior ISOLA Spine System, BOWTI Anterior Buttress Staple Spinal System, DISCOVERY Screw System, EXPEDIUM Anterior Spine System, FRONTIER Anterior Scoliosis System, KANEDA Anterior Scoliosis System, KANEDA SR Anterior Spinal System, M-2 Anterior Plate System, MOUNTAINEER Laminoplasty System, PROFILE Anterior Thoracolumbar Plate System, UNIVERSITY PLATE Anterior System, VIPER F2 Facet Fixation System

Nov 20, 2019
90 days to decision

K192281 · Product code: MRW · Orthopedic
Source: <https://www.510kdatabase.net/k192281/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Aug 22, 2019
Decision date	Nov 20, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medos International SARL
Location	Raynham, MA, US
Contact	Sergio M. Cordeiro
510(k) history	96 submissions · 96 cleared · 2010-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192281/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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