

K191212 CrossOver Cross Connectors, DePuy PULSE Thoracolumbar Screw System, EXPEDIUM Fenestrated Screw System, EXPEDIUM SFX Cross Connectors, EXPEDIUM Spine System, EXPEDIUM VERSE Spine System, E-Z Link Cross Connectors, ISOLA Spine System, MONARCH Spine System, MOSS MIAMI Spine System, TiMX Low Back System, VIPER Fenestrated Screw System, VIPER PRIME System, VIPER PRIME Fenestrated Screws, VIPER SAI (Sacral-Alar-Iliac), VIPER System, VIPER 2 System, VSP Spine System

Sep 24, 2019
141 days to decision

K191212 · Product code: PGM · Orthopedic
Source: <https://www.510kdatabase.net/k191212/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Growing Rod System (PGM)
Date received	May 6, 2019
Decision date	Sep 24, 2019
Days to decision	141 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/k191212/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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