

**K242361 OZARK Cervical Plate System**Nov 7, 2024  
90 days to decisionK242361 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k242361/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Aug 9, 2024
Decision date	Nov 7, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PYRENEES® Cervical Plate System; EVEREST® Spinal System; MESA® Spinal System; MESA® Small Stature Spinal System; CASPIAN® Spinal System; DENALI® Spinal System; DENALI® MI Spinal System; YUKON OCT Spinal System; Xia® 3 Spinal System; K2M Patient Specific; CASCADIA™ Interbody System; CAYMAN® Plate System; CAYMAN® Plate System-MI

**APPLICANT**

---

Company	<b>Stryker Spine</b>
Location	Allendale, NJ, US
Contact	Isabel Garza
510(k) history	74 submissions · 73 cleared · 2004-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242361/> 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 13, 2026