

K213901 Cyclops™ Anterior Cervical Plate SystemJan 7, 2022
24 days to decisionK213901 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k213901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 14, 2021
Decision date	Jan 7, 2022
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Degen Medical
Location	Florence, SC, US
Contact	Craig Black
510(k) history	16 submissions · 16 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Secure BioMed Evaluations
Contact	Linda Braddon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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