

K220379 IMPEACE and IMPEACE-Uni Anterior Cervical Plate SystemMar 3, 2022
21 days to decisionK220379 · Product code: **KWQ** · Orthopedic
Source: <https://www.510kdatabase.net/k220379/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 10, 2022
Decision date	Mar 3, 2022
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medynus, Inc.
Location	Irvine, CA, US
Contact	David Shin
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Eerkie Corporation
Contact	Jeena Mathai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220379/>; 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 26, 2026