FDA 510(k) Premarket Notification

CLEARED

K220379 IMPEACE and IMPEACE-Uni Anterior Cervical Plate System

Mar 3, 2022
21 days to decision

K220379 · 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