FDA 510(k) Premarket Notification

# K210182 PANAMA™ Anterior Cervical Plate (ACP) System

**CLEARED**

Apr 7, 2021
72 days to decision

K210182 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k210182/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Appliance, Fixation, Spinal Intervertebral Body (KWQ) |
| Date received | Jan 25, 2021 |
| Decision date | Apr 7, 2021 |
| Days to decision | 72 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Flospine** |
| Location | Fr. Myers, FL, US |
| Contact | Peter Harris |
| 510(k) history | 4 submissions · 4 cleared · 2014-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **BioVera, Inc.** |
| Contact | Robert A Poggie |

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