FDA 510(k) Premarket Notification

K230026 SQUALE

CLEARED

Mar 28, 2023
83 days to decision

K230026 · Product code: **ODP** · Orthopedic
Source: https://www.510kdatabase.net/k230026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Jan 4, 2023
Decision date	Mar 28, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Implanet, S.A.**
Location	Philedelphia, PA, US
Contact	Régis Le Couëdic
510(k) history	15 submissions · 15 cleared · 2012-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kelliann H Payne

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