

K220641 Barrigel Injectable GelMay 26, 2022
83 days to decisionK220641 · Product code: **OVB** · Radiology
Source: <https://www.510kdatabase.net/k220641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hydrogel Spacer (OVB)
Date received	Mar 4, 2022
Decision date	May 26, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Palette Life Sciences
Location	Santa Barbara, CA, US
Contact	David Goodnough
510(k) history	1 submissions · 1 cleared · 2022-2022

CLINICAL EVIDENCE - NCT04189913

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04189913

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220641/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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