

K250267 Visalys® Bulk Fill 1 x 4 g Syringe (15060)Mar 14, 2025
43 days to decisionK250267 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k250267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Jan 30, 2025
Decision date	Mar 14, 2025
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Visalys® Bulk Fill 15 x 0.25 g Caps (15062); Visalys® Bulk Flow 1 x 2 g Syringe (15064); Visalys® Bulk Flow 15 x 0.25 g Caps (15066); Visalys® Bulk Flow Intro pack (15067); Visalys® Bulk Intro pack (15068)

APPLICANT

Company	Kettenbach GmbH & Co. KG
Location	Eschenburg, DE
Contact	Marleen Steger
510(k) history	13 submissions · 13 cleared · 2008-2025

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