

K230333 Profisil Fluoride Varnish Combi pack (14801), Profisil Fluoride Varnish Normal pack mint (14802), Profisil Fluoride Varnish Normal pack berry (14804), Profisil Fluoride Varnish Normal pack unflavored (14806), Profisil Fluoride Varnish Sample pack (14800)Jul 24, 2023
167 days to decisionK230333 · Product code: **LBH** · Dental
Source: <https://www.510kdatabase.net/k230333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Varnish, Cavity (LBH)
Date received	Feb 7, 2023
Decision date	Jul 24, 2023
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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