

K973513 SINFONY DENTIN, OPAQUE-DENTIN, ENAMEL, ENAMEL MODIFIER, TRANSPARENT OPAL, SINFONY MAGIC MODIFIERS, SINFONY OPAQUER

Dec 22, 1997
96 days to decision

K973513 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k973513/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 17, 1997
Decision date	Dec 22, 1997
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Espe GmbH & Co. Kg.
Location	Seefeld, DE
Contact	BARBARA WAGNER-SCHUH
510(k) history	17 submissions · 17 cleared · 1995-1998

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Device record: <https://www.510kdatabase.net/k973513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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