

K990315 MONOPAQUEMar 4, 1999
31 days to decisionK990315 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k990315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Feb 1, 1999
Decision date	Mar 4, 1999
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ivoclar North America, Inc.
Location	Amherst, NY, US
Contact	PETER P MANCUSO
510(k) history	131 submissions · 131 cleared · 1989-2001

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