

K994012 TEMPOFIT, MODEL 02693Feb 16, 2000
82 days to decisionK994012 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k994012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Nov 26, 1999
Decision date	Feb 16, 2000
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Detax GmbH & Co. KG
Location	Amsterdam, NL
Contact	BARRY HALE
510(k) history	5 submissions · 5 cleared · 2000-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026