

K261485 Tetric plus Fill

Jul 1, 2026
57 days to decision

K261485 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k261485/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	May 5, 2026
Decision date	Jul 1, 2026
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Tetric plus Flow

APPLICANT

Company	Ivoclar Vivadent, Inc.
Location	Amherst, NY, US
Contact	Anderjeet Gulati
Website	https://www.ivoclar.com
510(k) history	66 submissions · 66 cleared · 2001-2026

Ivoclar Vivadent, Inc. is a dental solutions provider based in Amherst, US. The company develops modern products for dental practitioners and laboratory technicians. The company has received FDA 510(k) clearances from total submissions since 2001. Dental devices represent 97% of its regulatory portfolio. The latest clearance was issued in 2026, confirming active market engagement. Recent cleared devices include restorative materials, adhesives, CAD-on restorations, bulk-fill composites, and curing lights. The product portfolio spans chairside and laboratory workflows for ...