

**K103474 ENA TEMP AND ENAMEL PLUS TEMP (TWO  
DIFFERENT PROPRIETARY NAMES FOR THE SAME PRODUCT)**Feb 7, 2011  
73 days to decisionK103474 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k103474/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Nov 26, 2010
Decision date	Feb 7, 2011
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Micerium S.P.A.</b>
Location	Avegno, Genoa, IT
Contact	SSA CARLA TAZZER
510(k) history	6 submissions · 6 cleared · 2006-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103474/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026