

**K062906 ENA HFO COMPOSITE SYSTEM**Nov 17, 2006  
51 days to decisionK062906 · Product code: **EBF** · DentalSource: <https://www.510kdatabase.net/k062906/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 27, 2006
Decision date	Nov 17, 2006
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062906/> 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