

K151912 AIR-FLOW handy 3.0 PLUSFeb 3, 2016
205 days to decisionK151912 · Product code: **EFB** · Dental
Source: <https://www.510kdatabase.net/k151912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jul 13, 2015
Decision date	Feb 3, 2016
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	E.M.S Electro Medical Systems S.A
Location	North Attleboro, MA, US
Contact	Suzanne Fassio-Hardy
510(k) history	28 submissions · 28 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151912/> 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 3, 2026