

K082827 A-DEC/W&H PROFIN RECIPROCATING CONTRA-ANGLE HANDPIECE ATTACHMENTJan 7, 2009
104 days to decisionK082827 · Product code: EFB · Dental
Source: <https://www.510kdatabase.net/k082827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Sep 25, 2008
Decision date	Jan 7, 2009
Days to decision	104 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	A-Dec, Inc.
Location	Newberg, OR, US
Contact	THOMAS H LOUISELL
Website	http://www.a-dec.com/
510(k) history	69 submissions · 69 cleared · 1989-2022

A-Dec, Inc. is a dental equipment manufacturer based in Newberg, Oregon. The company designs and produces integrated dental operator systems, delivery equipment, handpieces, and mechanical room solutions for dental practices worldwide. A-Dec has maintained a strong FDA 510(k) regulatory record since 1989. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. All cleared devices fall within the Dental category, reflecting the company's specialization in dental equipment and accessories. The latest clearance on record dates to 2...