

K010127 W & H ASSISTINAOct 5, 2001
275 days to decisionK010127 · Product code: **EFB** · DentalSource: <https://www.510kdatabase.net/k010127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Dental (EFB)
Date received	Jan 3, 2001
Decision date	Oct 5, 2001
Days to decision	275 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	A-Dec, Inc.
Location	Newberg, OR, US
Contact	LOVENA STANDRIDGE
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 operatory 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...
