

K000967 4635 ASSISTANT'S INSTRUMENTATIONMay 3, 2000
37 days to decisionK000967 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k000967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Mar 27, 2000
Decision date	May 3, 2000
Days to decision	37 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...
