FDA 510(k) Premarket Notification

K940893 A-DEC RADIUS 2122/2132

CLEARED

Jul 12, 1994
137 days to decision

K940893 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k940893/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Feb 25, 1994
Decision date	Jul 12, 1994
Days to decision	137 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**A-Dec, Inc.**
Location	Newberg, OR, US
Contact	PATRICK RIDENOUR
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...