FDA 510(k) Premarket Notification

K032070 ELCACAM

CLEARED

Aug 27, 2003
55 days to decision

K032070 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k032070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Jul 3, 2003
Decision date	Aug 27, 2003
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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