FDA 510(k) Premarket Notification

K213932 A-dec 300, A-dec 500

CLEARED

Mar 2, 2022
76 days to decision

K213932 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k213932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Dec 16, 2021
Decision date	Mar 2, 2022
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**A-Dec, Inc.**
Location	Newberg, OR, US
Contact	Raquel Peregrino de Brito
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...