

**K100647 A-DEC/W&H SYNEA SONIC SCALER HANDPIECE,
MODELS ZA-55, ZA-55 L, ZA-55 LM, ZA-55M, SF1LM**Jul 9, 2010
123 days to decisionK100647 · Product code: ELC · Dental
Source: <https://www.510kdatabase.net/k100647/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Scaler, Ultrasonic (ELC) |
| Date received | Mar 8, 2010 |
| Decision date | Jul 9, 2010 |
| Days to decision | 123 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | A-Dec, Inc. |
| Location | Newberg, OR, US |
| Contact | THOMAS H 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 operator 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...