

**K964271 IGN 500 TM WATER CLEANING UNIT WITH CALBENIUM LIQUID**Dec 19, 1997  
420 days to decision

K964271 · Product code: EIA · Dental

Source: <https://www.510kdatabase.net/k964271/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Oct 25, 1996
Decision date	Dec 19, 1997
Days to decision	420 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Airel-West</b>
Location	Washington, DC, US
Contact	DANIEL A KRACOV
510(k) history	1 submissions · 1 cleared · 1997-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964271/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated July 2, 2026