

**K902244 RASTRONICS CCI 8**Oct 5, 1990  
140 days to decisionK902244 · Product code: **ETW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k902244/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW) |
| Date received         | May 18, 1990  |
| Decision date         | Oct 5, 1990   |
| Days to decision      | 140 days  |
| Third-party review    | No  |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Rastronics USA, Inc.</b>           |
| Location       | Mountainside, NJ, US                  |
| Contact        | ROBERT P WOLF                         |
| 510(k) history | 5 submissions · 5 cleared · 1985-1990 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k902244/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026