

**K853114 ROTALOK WRIST STRAP, ROTALOK SKIN  
RETRACTOR**Aug 6, 1985  
13 days to decisionK853114 · Product code: **GAD** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k853114/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Retractor (GAD)                    |
| Date received         | Jul 24, 1985                       |
| Decision date         | Aug 6, 1985                        |
| Days to decision      | 13 days                            |
| Third-party review    | No                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Australian Biomedical Corporation , Ltd.</b> |
| Location       | Australia, US                                   |
| Contact        | J. D COOK                                       |
| 510(k) history | 5 submissions · 5 cleared · 1985-1987           |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853114/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026