

**K860095 DIGIKIT NONPNEUMATIC TOURNIQUET**Jan 24, 1986  
14 days to decisionK860095 · Product code: **KCY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k860095/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Tourniquet, Pneumatic (KCY)        |
| Date received         | Jan 10, 1986                       |
| Decision date         | Jan 24, 1986                       |
| Days to decision      | 14 days                            |
| Third-party review    | No                                 |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Orthofab, Inc.</b>                 |
| Location       | Cottage Grove, MN, US                 |
| Contact        | THOMAS H BARROWS                      |
| 510(k) history | 7 submissions · 7 cleared · 1985-1997 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k860095/>; 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 June 29, 2026