

**K980689 FRIDDLE HALO SYSTEM, FRIDDLE MRI HALO SYSTEM**

Feb 18, 1999  
360 days to decision

K980689 · Product code: **HAX** · Neurology  
Source: <https://www.510kdatabase.net/k980689/>

**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Tong, Skull For Traction (HAX)     |
| Date received         | Feb 23, 1998                       |
| Decision date         | Feb 18, 1999                       |
| Days to decision      | 360 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Friddle&amp;apos;S Orthopedic Appliances, Inc.</b> |
| Location       | Honea Path, SC, US                                    |
| Contact        | FRANK E FRIDDLE, JR.                                  |
| 510(k) history | 1 submissions · 1 cleared · 1999-1999                 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k980689/>; 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 June 30, 2026