

**K042948 I OPEN 0.36 T-MAGNETIC RESONANCE IMAGING SYSTEM**Nov 3, 2004  
8 days to decisionK042948 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k042948/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received         | Oct 26, 2004                                     |
| Decision date         | Nov 3, 2004                                      |
| Days to decision      | 8 days   |
| Third-party review    | Yes  |
| Summary / Statement   | Summary  |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Wandong Medical</b>                |
| Location       | Beijing, CN                           |
| Contact        | WANG WEIMIN                           |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042948/> 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 18, 2026