

**K092899 OPER SERIES OPEN TYPE PERMANENT-MAGNET  
MRI SYSTEM, MODEL: OPER-0.3, -0.35, -0.4**Nov 10, 2009  
50 days to decisionK092899 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k092899/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Sep 21, 2009
Decision date	Nov 10, 2009
Days to decision	50 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ningbo Xingaoyi Magnetism Co., Ltd.</b>
Location	Yuyao, Zhejiang, CN
Contact	JIANG MOWEN
510(k) history	1 submissions · 1 cleared · 2009-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092899/> 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 17, 2026