

**K123091 VISIUS WIRELESS COILS, 1.5T/ VISIUS WIRELESS COILS, 3T**

Dec 27, 2012  
86 days to decision

K123091 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k123091/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Coil, Magnetic Resonance, Specialty (MOS) |
| Date received         | Oct 2, 2012                               |
| Decision date         | Dec 27, 2012                              |
| Days to decision      | 86 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Imris, Inc.</b>                      |
| Location       | Rockville, MD, US                       |
| Contact        | Sanjay Shah                             |
| 510(k) history | 14 submissions · 14 cleared · 2006-2015 |

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

Device record: <https://www.510kdatabase.net/k123091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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