

**K153044 Sentimag System, Sentimark Magnetic Marker System**Mar 2, 2016  
135 days to decisionK153044 · Product code: **PBY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k153044/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Temporary Tissue Marker (PBY)      |
| Date received         | Oct 19, 2015                       |
| Decision date         | Mar 2, 2016                        |
| Days to decision      | 135 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Endomagnetics Ltd.,</b>            |
| Location       | Cambridge, GB                         |
| Contact        | ANDREW SHAWCROSS                      |
| 510(k) history | 5 submissions · 5 cleared · 2016-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153044/>; 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 May 27, 2026