

**K934373 MOBILE SOPHIE MODIFICATION**Apr 7, 1994  
211 days to decisionK934373 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k934373/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Mammographic (IZH)  |
| Date received         | Sep 8, 1993                        |
| Decision date         | Apr 7, 1994                        |
| Days to decision      | 211 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Planned OY</b>                       |
| Location       | Helsinki, FI                            |
| Contact        | SARI MYLLYRINNE                         |
| 510(k) history | 20 submissions · 20 cleared · 1992-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934373/> 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 14, 2026