

K021945 PLANMED SOPHIE & SOPHIE CLASSIC (WITH DIGISPOT AND CYTOGUIDE)Feb 21, 2003
253 days to decisionK021945 · Product code: **IZH** · Radiology
Source: <https://www.510kdatabase.net/k021945/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Mammographic (IZH) |
| Date received | Jun 13, 2002 |
| Decision date | Feb 21, 2003 |
| Days to decision | 253 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Planmed OY |
| Location | Helsinki, FI |
| Contact | BOB PIENKOWSKI |
| 510(k) history | 20 submissions · 20 cleared · 1992-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021945/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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