

K250429 DSPS-Prominent® baseplate, MR (113820)Mar 19, 2025
33 days to decisionK250429 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k250429/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Accelerator, Linear, Medical (IYE) |
| Date received | Feb 14, 2025 |
| Decision date | Mar 19, 2025 |
| Days to decision | 33 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | DSPS-Prominent® baseplate (113120); DSPS-Prominent® Cradle-I (113140); DSPS-Prominent® Cradle-II (113150); DSPS-Prominent® Cradle-III (113160); DSPS-Prominent® Cradle-IV (113170); DSPS-Prominent® Cradle-VI (113180); DSPS-Prominent® Cradle-VII (113260); Mask DSPS®-PROSCVRL set/5 (113760); Mask DSPS®-PROSC set/5 (113770); Mask DSPS®-PROSCVR set/5 (113780); Mask DSPS®-PROSCL set/5 (113790); Mask DSPS®-PROSHVRL set/5 (113890); Mask DSPS®-PROSH set |

APPLICANT

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|----------------|---------------------------------------|
| Company | Macromedics BV |
| Location | Waddinxveen, NL |
| Contact | Elizabeth Hajos |
| 510(k) history | 5 submissions · 5 cleared · 2015-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250429/> 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 13, 2026