

**K231579 MOLLI 2**Oct 26, 2023  
148 days to decisionK231579 · Product code: **NEU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231579/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Marker, Radiographic, Implantable (NEU) |
| Date received         | May 31, 2023                            |
| Decision date         | Oct 26, 2023                            |
| Days to decision      | 148 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Molli Surgical, Inc.</b>           |
| Location       | Toronto, CA                           |
| Contact        | Joseph De Croos                       |
| 510(k) history | 5 submissions · 5 cleared · 2021-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231579/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026