

K041579 MEDELA SINGLE USE SILC CUP, MODEL 077.0791Apr 21, 2005
311 days to decisionK041579 · Product code: **HDB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k041579/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Extractor, Vacuum, Fetal (HDB) |
| Date received | Jun 14, 2004 |
| Decision date | Apr 21, 2005 |
| Days to decision | 311 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medela AG |
| Location | Ch-6340 Baar, CH |
| Contact | WERNER FREI |
| 510(k) history | 30 submissions · 30 cleared · 2002-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041579/> 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 June 28, 2026