

K052642 SUTURING WASHERJan 17, 2006
113 days to decisionK052642 · Product code: **MAB** · Cardiovascular
Source: <https://www.510kdatabase.net/k052642/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Marker, Cardiopulmonary Bypass (vein Marker) (MAB) |
| Date received | Sep 26, 2005 |
| Decision date | Jan 17, 2006 |
| Days to decision | 113 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | First Call, Inc. |
| Location | Derby, CT, US |
| Contact | DINA L WEISSMAN |
| 510(k) history | 1 submissions · 1 cleared · 2006-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052642/> 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 July 1, 2026