

**K050770 MODIFICATION TO ACCUFUSER, ACCUFUSER PLUS
STANDARD PROCEDURE KIT**Apr 14, 2005
20 days to decisionK050770 · Product code: **MEB** · General Hospital
Source: <https://www.510kdatabase.net/k050770/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Infusion, Elastomeric (MEB) |
| Date received | Mar 25, 2005 |
| Decision date | Apr 14, 2005 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mckinley Medical, LLC |
| Location | Wheat Ridge, CO, US |
| Contact | RALPH D COOEY |
| 510(k) history | 2 submissions · 2 cleared · 2005-2006 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050770/>. 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 30, 2026