

K012754 EZ SET INFUSION SETAug 27, 2001
11 days to decisionK012754 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k012754/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Aug 16, 2001 |
| Decision date | Aug 27, 2001 |
| Days to decision | 11 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Animas Corp. |
| Location | Frazer, PA, US |
| Contact | MICHAEL J ANDREWS |
| 510(k) history | 10 submissions · 10 cleared · 2000-2008 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012754/> 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 25, 2026