FDA 510(k) Premarket Notification

# K012429 SURESET INFUSION SET, MODEL 8023

**CLEARED**

Nov 6, 2001
98 days to decision

K012429 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k012429/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Jul 31, 2001 |
| Decision date | Nov 6, 2001 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Applied Diabetes Research, Incorporated** |
| Location | Chapel Hill, NC, US |
| Contact | CHARLES H KYPER |
| 510(k) history | 3 submissions · 3 cleared · 2001-2003 |