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# 510(k) Premarket Notification Database

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|---|---|
| **Device Classification Name** | set, administration, intravascular |
| **510(k) Number** | K003854 |
| **Device Name** | INTRAVASCULAR ADMINISTRATION SET |
| **Applicant** | INFUSION DEVICES, INC.<br>6329 w. waterview ct.<br>mccordsville, IN 46055 |
| **Contact** | paul e dryden |
| **Regulation Number** | 880.5440 |
| **Classification Product Code** | FPA |
| **Date Received** | 12/13/2000 |
| **Decision Date** | 02/05/2001 |
| **Decision** | substantially equivalent (SE) |
| **Classification Advisory Committee** | General Hospital |
| **Review Advisory Committee** | General Hospital |
| **Statement/Summary/Purged Status** | Summary only |
| **summary** | summary |
| **Type** | Traditional |
| **Reviewed by Third Party** | No |
| **Expedited Review** | No |

Database Updated 03/06/2009

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