

K121089 NMI PICC IIIAug 23, 2012
135 days to decisionK121089 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k121089/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS) |
| Date received | Apr 10, 2012 |
| Decision date | Aug 23, 2012 |
| Days to decision | 135 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Navilyst Medical, Inc. |
| Location | Marlborough, MA, US |
| Contact | Lorraine M Hanley |
| Website | http://www.navilystmedical.com/ |
| 510(k) history | 35 submissions · 33 cleared · 2009-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121089/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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