

K820767 BIOPOLAR TINED ENDOCARDIAL LEAD 403B/60Apr 9, 1982
18 days to decisionK820767 · Product code: **DTB** · CardiovascularSource: <https://www.510kdatabase.net/k820767/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Permanent Pacemaker Electrode (DTB) |
| Date received | Mar 22, 1982 |
| Decision date | Apr 9, 1982 |
| Days to decision | 18 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Siemens Elema AB |
| Location | Mchenry, IL, US |
| 510(k) history | 63 submissions · 60 cleared · 1978-2003 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k820767/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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