

K042399 MODIFICATION TO SHORT INTRODUCER SHEATHDec 17, 2004
105 days to decisionK042399 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k042399/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Sep 3, 2004 |
| Decision date | Dec 17, 2004 |
| Days to decision | 105 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rex Medical, L.P. |
| Location | Great Neck, NY, US |
| Contact | SUSAN D GOLDSTEIN-FALK |
| 510(k) history | 8 submissions · 8 cleared · 2004-2021 |

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