

**K130333 CAPIX RX HOLLOW FIBER OXYGENATOR
WITH/WITHOUT HARDSHELL RESERVOIR**Mar 13, 2013
30 days to decisionK130333 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k130333/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Oxygenator, Cardiopulmonary Bypass (DTZ) |
| Date received | Feb 11, 2013 |
| Decision date | Mar 13, 2013 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Terumo Cardiovascular Systems Corp. |
| Location | Elkton, MD, US |
| Contact | SUZANNE GRENIER |
| 510(k) history | 43 submissions · 43 cleared · 2000-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130333/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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