

K833662 CARDIOPLEGIA SYSTEM CCS-XXX SERIESDec 29, 1983
72 days to decisionK833662 · Product code: **DTR** · CardiovascularSource: <https://www.510kdatabase.net/k833662/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Heat-exchanger, Cardiopulmonary Bypass (DTR) |
| Date received | Oct 18, 1983 |
| Decision date | Dec 29, 1983 |
| Days to decision | 72 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Gish Biomedical, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 75 submissions · 75 cleared · 1983-2009 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k833662/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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