FDA 510(k) Premarket Notification

# K183623 LifeSPARC Pump, LifeSPARC Controller

**CLEARED**

Jul 9, 2019
195 days to decision

K183623 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k183623/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM) |
| Date received | Dec 26, 2018 |
| Decision date | Jul 9, 2019 |
| Days to decision | 195 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Cardiacassist, Inc.** |
| Location | Pittsburgh, PA, US |
| Contact | Greg Johnson |
| 510(k) history | 21 submissions · 21 cleared · 2000-2024 |