FDA 510(k) Premarket Notification

# K082321 TERUMO ROCSAFE HYBRID PERFUSION SYSTEM

**CLEARED**

Feb 13, 2009
184 days to decision

K082321 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k082321/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM) |
| Date received | Aug 13, 2008 |
| Decision date | Feb 13, 2009 |
| Days to decision | 184 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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