

K111438 REKA E100Sep 12, 2011
111 days to decisionK111438 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k111438/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Electrocardiograph (DPS) |
| Date received | May 24, 2011 |
| Decision date | Sep 12, 2011 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Reka Pte, Ltd. |
| Location | Summerville, SC, US |
| Contact | LARRY PETERSEN |
| 510(k) history | 1 submissions · 1 cleared · 2011-2011 |

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